IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Wm. A. KNAUS et al.	)	**Group Art Unit: 3626**
	)	
Application No: 09/816,152	)	**Examiner: Lena Najarian**
	)	
Filed: March 26, 2001	)	
	)	

Title: BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROLAND MANAGEMENT OF MEDICAL RECORDS

MAIL STOP = APPEAL BRIEF - PATENTS

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF ON APPEAL

Sir:

This Appeal is from the Examiner's Final Rejection of claims 1-59, and the Notice of Panel Decision from Pre-Appeal Brief Review of these same claims.

REAL PARTY IN INTEREST

The real party in interest is Patient Command, Inc., a Delaware corporation with its place of business in McLean, Virginia.

RELATED APPEALS AND INTERFERENCES

A Notice of Appeal has been filed and a Pre-Appeal Brief Request for Review has been received by the United States Patent and Trademark Office (USPTO") in U.S. Patent Application 09/822,261, which is a continuation of the instant application. To the best of the undersigned's knowledge, there is no other related Appeal or Interference within the meaning of 37 CFR 1.192(c).

STATUS OF CLAIMS

Claims 1-59 are currently pending in the application and these same claims are before the Board. A copy of these claims is appended hereto.

STATUS OF AMENDMENTS

Appellant last amended the claims on November 1, 2005 to put the claims in better conditioned for Appeal. These amendments were not entered by the Examiner. The last entered claim amendments were submitted in Appellant's Reply of July 7, 2005 and are appended hereto.

SUMMARY OF CLAIMED SUBJECT MATTER

Appellant's claimed invention is directed to a broad-band, computer-based networked system of medical health records (specification, page 1, lines 9-11). The system comprises a collection of patient-based, as contrasted with hospital-based or institutional-based electronic medical records that are encrypted, or secured when collected, accessed, input, viewed integrated and/or transmitted (*Id.* at page 7, lines 4-5 and lines 12-16, and page 13, lines 21-23). The electronic medical records are obtained from a plurality of sources, such as hospitals, doctors and clinicians, to name a few (*Id.* at page 13, lines 20-21 and page 18, lines 25-27). At least one medical record of the collection possesses the characteristic on non-repudiation, such that the medical information contained is as good or better than exists at the source from which the medical record was obtained (*Id.* at page 17, lines 14-17 and page 21, lines 20-24). The electronic medical record may be transmitted in whole or in part, and may be supplemented with additional information (*Id.* at page 23, lines 9-10 and lines 15-16).

In one embodiment of the broad-band, computer-based networked system of medical health records, at least one medical record is vetted and can contain corrections and notations of incorrect information as well as notation or linking of errors and/or anomalies. The vetted information can also contain notations or linking of discrepancies. Additionally, combinations of incorrect information, errors, anomalies and/or discrepancies can be corrected, linked and/or noted (*Id.* at page 20, lines 16-20).

Another embodiment of the claimed invention comprises a broad-band, computer-based networked system for individual control and management of electronic medical records having a plurality of medical records representing a plurality of persons. These medical records comply

with federal standards of privacy and security (*Id.* at page 14, lines 26-28). Further, the medical information of at least one medical record of the plurality has been vetted, such that the medical information is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation (*Id.* at page 17, lines 14-17 and page 21, lines 23-24).

A further embodiment of the computer-based networked system allows for non-repudiation of medical information of medical records and these records are primary for treatment of the person whom each medical record pertains (*Id.* at page 17, lines 14-17). These records comply with the Health Insurance Portability and Accountability Act of 1996 as well as state standards of privacy and security. Access to the records is limited to the person whom the records pertain to or to others designated and authorized by that person (*Id.* at page 14, line 21 to page 15, line 1).

Another embodiment of the claimed invention comprises a method for creating an accessible electronic medical records database. This method comprises obtaining and compiling a medical record pertaining to a patient, determining the accuracy and correctness of medical information within each medical record, electronically inputting the medical information within each medical record into a secure computer database containing other medical records, and allowing the patient and those authorized by the patient access to the patient's medical record wherein access to all other medical records is blocked (*Id.* at page 8 lines 6-9 and page 17, lines 14-17 and page 14, lines 1-5).

Still another embodiment is a business method operating and maintaining a secure database of medical records containing medical information of many persons obtained from a plurality of sources (*Id.* at page 7, lines 23-25). Each medical record is accessible through transmission pathways and only by the person to whom the medical record pertains and those authorized by that person (*Id.* at page 15, lines 1-3). Additionally, accuracy and correctness of the medical information within at least one medical record is determined to be as good or better than exists at the source from which the at least one medical record was obtained (*Id.* at page 17, lines 14-17).

Yet another embodiment of the claimed invention is directed to a method for integrating medical records to create a certified medical record database by obtaining medical information from one or more healthcare sources for a plurality of patients, electronically inputting all of the medical information obtained into a secure computer database to create medical records and

certifying that each of the medical records meet one of a plurality of certification standards established by a service provider to create the certified medical record database (*Id.* at page 17, lines 21-24 and page 15, lines 12-15).

In another embodiment of the claimed invention, a computer system for management of patient-based medical records has a database of medical records pertaining to one or more subjects, a receiver for receiving the medical information pertaining to the medical records from one or more senders, a process for verifying that the medical information received is accurate and correct by at least vetting the medical information, a process for authorizing the senders and the additional receivers according to a set of rules, and a transmitter for transmitting at least a portion of the medical records to one or more additional receivers and authorization for authorizing the senders and receivers according to a set of rules (*Id.* at page 18, lines 7-13, page 17, lines 14-17, page 13, lines 25-26, page 7, lines 18-19 and figure 1).

In another embodiment of the claimed invention, the system for management of patient-based medical records database is secure and complies with state and federal standards of privacy and security and with the Health Insurance Portability and Accountability Act of 1996 (*Id.* at page 14, lines 26-28).

In a further embodiment of the claimed invention, an electronic database of medical records is created and compiled wherein the medical information contained within the medical records is more accurate and correct as compared to those sources from which the medical records were obtained (*Id.* at page 14, lines 14-17).

In a further embodiment of the claimed invention, medical records of the collection can be primary for treatment of the patient to whom the record pertains (*Id.* at figure 3). In another embodiment, the medical records may be accessed only by the patient or individuals authorized by the patient *Id.* at page 15, lines 1-3). The collection complies with federal and state standards of medical record privacy and security such as the Health Insurance Portability and Accountability Act of 1996 (*Id.* at page 14, lines 26-28).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

At issue is whether claims 1-59 are patentable over certain alleged prior art references. Also at issue is whether Appellant's Affidavit is sufficient to remove certain prior art references under 37 C.F.R. § 1.131.

GROUPING OF CLAIMS

The claims do not stand or fall together, but may be divided into three groups. The first group represents the claims rejected in view of Segal. The second group represents the claims rejected in view of Malik. The third group represents the claim that has not been properly examined.

Group I: Claim 1-59 and Segal

Pursuant to the final Office Action, claims 1-11, 17, 30, 31, 34-47, 51-55 and 57-59 stand rejected, under 35 U.S.C. § 102(e), as allegedly anticipated by Segal et al. (U.S. Patent Application Publication No. 2001 10041991; "Segal"). Claim 12 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Baker (PCASSO). Claims 13-15, 20-22, 25-29, 32-33 and 48-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Malik (U.S. Patent Application Publication No. 2001 0037219). Claim 16 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Shear (U.S. Patent No. 4,827,508). Claims 18-19 and 31 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Ertel (U.S. Patent No. 5,307,262). Claims 23 and 24 stand rejected, under 35 U.S.C. § 103(c), as allegedly obvious over Segal in view of Malik, and further in view of Ertel. Claim 56 stands rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Joao (U.S. Patent No. 6,283,761). Appellant respectfully traversed these rejections noting that Segal failed to disclose or suggest either alone of in combination with the other cited art references the instant claimed invention. For at least this reason, the rejections should fall. Further, a Rule 131 Declaration in which the inventors state that their claimed invention was conceived and reduced to practice prior to the filing date of the provisional application which became Segal was submitted on July 7, 2005 and resubmitted with claims charts on November 1, 2005. Accordingly, Segal either does not disclose of suggest Appellant's claims or is not a prior art reference. Either way, these rejections are overcome or moot.

Group II: Claims 13-15, 20-22, 25-29, 32-33 and 48-50 and Malik

Claims 13-15, 20-22, 25-29, 32-33 and 48-50 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Malik (U.S. Patent Application Publication No. 2001

0037219). Claims 23 and 24 stand rejected, under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Malik, and further in view of Ertel. Appellant respectfully traversed these rejections noting that Malik failed to disclose or suggest either alone of in combination with the other cited art references the instant claimed invention and this rejection should fall. Further, in view of the 131 Declaration provided, Malik is not prior art to the claimed invention and, thus, this rejection is either overcome or moot.

Group III Claim 37

Claim 37 stands rejected, under 35 U.S.C. § 102(e), as allegedly anticipated by Segal. Appellant respectfully traverses this rejection. In view of the fact that the Examiner failed to show in any of the cited art references elements of the claim 37, this claim should be declared allowable.

ARGUMENT

Appellant received a nonfinal Office Action, mail dated June 17, 2005, wherein Appellant's claims stood rejected, under 35 U.S.C. § 102(e), as allegedly anticipated by Segal et al. (US 2001/0041991; "Segal"), and also under 35 U.S.C. § 103(a), as allegedly obvious over Segal in view of Malik (US 2001/0037219; "Malik") and Segal in view of other prior art references.

In that Office Action, the Examiner, after improperly re-interpreting many of the elements of the claims, asserted that the claimed invention is disclosed and suggested in Segal and Malik. Appellant disagreed, noting that the actual claim elements were absent from both references. Appellant also furnished an affidavit under 37 C.F.R. § 1.131 with supporting evidence (the "Affidavit"), demonstrating that, in accordance with M.P.E.P. § 715, the inventors had conceived and/or reduced to practice the claimed invention prior to the filing dates of both Segal and Malik.

The Examiner next issued a final Office Action mail dated September 23, 2005, re-asserting the same rejections. No rejections were reconsidered and the Examiner refused to modify her re-interpretation of the claims. The Examiner also asserted that Appellant's Affidavit failed to demonstrate conception and/or reduction to practice "*of the whole invention claimed or something falling within the claims*" (final Office Action, page 15), because she was unable to

locate Appellant's invention in the Affidavit, and because Appellant failed to show a nexus between the Affidavit and the claimed invention. Because the Examiner's analysis contains a series of material errors, Appellant respectfully submits this Appeal.

Analysis of the examination of the claims to date at least reveals:

(1) a failure to deal with each claim, and in particular claim 37;

(2) confusion between two critical sections of the MPEP (37 CFR §§ 1.131 and 1.132), leading to a direct, erroneous, adverse impact on the Examiner's conclusions with regard to an affidavit submitted under § 1.131; and

(3) two mutually inconsistent interpretations of the word "actual" in the § 1.131 affidavit and asserted prior art which, when carefully compared, lead inevitably to a conclusion that either the prior art does not teach the claimed invention or, alternatively, that the § 1.1131 affidavit demonstrates the appellant's earlier invention of "accuracy" as found in the asserted prior art.

Taken together or separately, these errors in the examination demonstrate that all rejections in the final Office Action should be withdrawn, and a Notice of Allowance promptly issued.

I. Claim 37 Should be Declared Allowable.

In neither the non-final nor the final Office Action did the Examiner ever review certain claims. For example, there is no disclosure in any of the cited references relating to claim 37 with regard to the element: "is more accurate and correct as compared to those sources from which the medical records were obtained." None of the cited references discloses or suggests, and none of the Examiner's comments materially relates to, a computer-networked system where the medical records are *more* accurate than the records collected from the source sites where the records originated. Consequently, at least claim 37 should immediately be declared allowable.

II. Rejections of Claims 1-59 Under 35 U.S.C. § 102(e) and 35 U.S.C. § 103(a) in View of Segal are Erroneous.

A. Errors in the Examiner's Analysis of Appellant's § 1.131 Affidavit Demonstrate That the Rejections Based on Asserted Prior Art Must Be Withdrawn.

The Examiner committed at least two clear errors in rejecting Appellant's §.1.131 Affidavit. First, she erroneously required that there be a "nexus" between the Affidavit and the claimed invention (final Office Action, page 15). Second, the Examiner erroneously required that "the whole invention claimed or something falling within the claim" be located within the Affidavit (final Office Action, page 15).

As to the first error, there is no "nexus" requirement in 37 CFR §.1.131. Rather, the requirement for a "nexus" is found in §.1.132. This was repeatedly noted to the Examiner, yet the Examiner repeatedly asserted, without further comment, that Appellant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15).

Section 1.132 contains an explicit textual requirement for a "nexus" and §.1.131 does not. This textual difference precludes the Examiner from imposing a requirement for a nexus in § 1.131, as she has done. The omission of a "nexus" requirement in § 1.131, followed by the explicit textual inclusion of a "nexus" requirement in the very next section, § 1.132, in fact *requires* the Examiner to draw the negative inference that § 1.131 does not have a "nexus" requirement, and to recognize that "nexus" cannot be read into § 1.131 by implication or any other means. This analysis follows established rules of textual interpretation. For example, in a recent case the U.S. Supreme Court analyzed two sections of a statute dealing with jurisdiction. The first provision contained a jurisdictional bar (a provision stripping courts of jurisdiction), but that bar was not contained in the second section. The Court concluded that drawing the negative inference – that the section without the jurisdictional bar could only be read as not precluding jurisdiction – was *required*:

> A like inference follows *a fortiori* from *Lindh* in this case. "If . . . Congress was reasonably concerned to ensure that [§§ 1005(e)(2) and (3)] be applied to pending cases, it should have been just as concerned about [§ 1005(e)(1)], unless it had the different intent that the latter [section] not be applied to the general run of pending cases." *Id.*, at 329, 117 S. Ct. 2059, 138 L. Ed. 2d 481. If anything, the evidence of deliberate omission is stronger here than it was in *Lindh*. In *Lindh*, the provisions to be contrasted had been drafted separately but were later "joined together and . . . considered simultaneously when the language raising the implication was inserted." *Id.*, at 330, 117 S. Ct. 2059, 138 L. Ed. 2d 481. We observed that Congress' tandem review and approval of the two sets of provisions strengthened the presumption that the relevant omission was deliberate. *Id.*, at 331, 117 S. Ct. 2059, 138 L. Ed. 2d 481; see also *Field* v. *Mans,* 516 U.S. 59, 75, 116 S. Ct. 437, 133 L. Ed. 2d 351 (1995) ("The more apparently deliberate the

> contrast, the stronger the inference, as applied, for example, to contrasting statutory sections originally enacted simultaneously in relevant respects"). Here, Congress not only considered the respective temporal reaches of paragraphs (1), (2), and (3) of subsection (e) together at every stage, but omitted paragraph (1) from its directive that paragraphs (2) and (3) apply to pending cases only after having *rejected* earlier proposed versions of the statute that would have included what is now paragraph (1) within the scope of that directive. Compare DTA § 1005(h)(2), 119 Stat. 2743-2744, with 151 Cong. Rec. S12655 (Nov. 10, 2005) (S. Amdt. 2515); see *id.*, at S14257-S14258 (Dec. 21, 2005) (discussing similar language proposed in both the House and the Senate). Congress' rejection of the very language that would have achieved the result the Government urges here weighs heavily against the Government's interpretation. See *Doe* v. *Chao,* 540 U.S. 614, 621-623, 124 S. Ct. 1204, 157 L. Ed. 2d 1122 (2004).
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> . . . .
>
> Congress here expressly provided that subsections (e)(2) and (e)(3) applied to pending cases. It chose not to so provide -- after having been presented with the option -- for subsection (e)(1). The omission is an integral part of the statutory scheme that muddies whatever "plain meaning" may be discerned from blinkered study of subsection (e)(1) alone. The dissent's speculation about what Congress might have intended by the omission not only is counterfactual, but rests on both a misconstruction of the DTA and an erroneous view our precedents.

Hamdan v. Rumsfeld, 126 S. Ct. 2749, 2766 & 2769 (2006) (footnotes and internal citations omitted).

The Examiner's second error evinces an inexplicable disregard of the clear text of the MPEP § 715.02, because the Examiner erroneously asserts that Appellant must state the entirety of its claimed invention in the Affidavit in order for her to consider the Affidavit sufficient (final Office Action, page 15). This directly contravenes MPEP § 715.02, which states that Appellant *only* needs to show that the Affidavit contains *the elements of the claimed invention that are found in the supposed prior art:*

> [A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. *If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient*....(Emphasis added.)

The Examiner's analytical approach to Appellant's Affidavit is contrary to the MPEP, and thus clear error. Segal should be removed as a prior art reference in view of Appellant's Affidavit.

Moreover, Appellant respectfully asserts that the Examiner failed properly to examine the Affidavit as she is required to do under M.P.E.P. 715. Appellant's Affidavit includes evidence establishing conception and reduction to practice of Appellant's claimed invention sufficiently to overcome Segal as prior art. That evidence was initially provided on July 7, 2005, with the most relevant sections highlighted as a courtesy for the Examiner. Unfortunately the highlighting was lost when the Affidavit was processed by the PTO into electronic form, which is how it was received by the Examiner. Thus, what the Examiner received was not what Appellant filed, but an incomplete copy. This was an error by the PTO, but one which was readily apparent to the Examiner. The error could have been rectified had the Examiner simply telephoned the undersigned. It is not Appellant's duty to highlight the Affidavit evidence. The burden properly to examine the Affidavit lies with the PTO, not with the Appellant. It was neither unreasonable nor burdensome for the Examiner to review the Affidavit, and her failure to do so is clear error.

B. Errors in Examining Appellant's Claims of "Certification" and "Non-Repudiation," Particularly a Teaching Away, Show Hindsight and Violation of the MPEP, So That Rejections for Failure to Disclose the Claimed Invention and for Obviousness Must Be Withdrawn.

1) The Claim Element of "Nonrepudiation"

Nonrepudiation is positively recited as an element of Appellant's claimed invention (e.g., claims 1, 8, 9, 25, 26 and 54). As recited in claim 1, medical information contained within medical records is verified as accurate and correct such that: "*one or more records of the collection possess a characteristic of nonrepudiation.*" This element is also clear from the specification: *"Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon"* (specification, page 17, lines 14-17). This claim element of Appellant's invention is nowhere to be found in Segal.

In a preferred embodiment (e.g., claims 23, 24, 31), nonrepudiation is attained from an accurate medical record that is then subjected to a separate additional step of verification or vetting (*also see* specification, page 17, lines 11-21). Therefore, as is unambiguously set forth in one embodiment, accuracy alone does not create the element of nonrepudiation. For at least this reason, nonrepudiation is not disclosed or suggested in Segal.

2) The Claim Element of "Certification"

Certification is positively recited as an element of Appellant's claimed invention. (e.g., claims 10, 11, 21, 22, 41-43 and 45). As recited in claim 10, the invention comprises a collection of medical records wherein "*each medical record is certified as accurate.*" The quality assurance and/or accuracy alleged by the Examiner to be in Segal are not disclosures of, or make obvious, the instantly claimed certification. Segal's proposition is only that electronic medical records are inherently more accurate than paper-based records. Whether or not this is true is irrelevant here, because a mere desire for accuracy is not Appellant's certification. As stated by Appellant: "*The invention may include a form of medical record that can be completed at one of a plurality of certification levels*" (specification, page 15, lines 12-13). "*Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered ....*" (specification, page 15, lines 22-25; and claims 20, 37, 43). Segal's statement that electronic medical records are inherently more accurate than paper records is not a person's or entity's certification of accuracy as claimed by Appellant, and for that reason is neither disclosed nor suggested in Segal.

3) Segal Does Not Disclose or Suggest the Claimed Invention

Segal fails to disclose or suggest at least the elements of "certification of medical records" (claims 10, 11, 21, 22, 41-43 and 45) or "nonrepudiation of medical records" (claims 1, 8, 9, 25, 26 and 54) as these elements are claimed by Appellant. The Examiner's re-interpretation of these elements is based on a Procrustean distortion of claim terms for the obvious purpose of shoe-horning these elements into portions of Segal. This is purposeful, and obvious, hindsight.

The Examiner asserts that "nonrepudiation of medical records" and "certification of medical records" are disclosed in Segal (*see* final Office Action, page 18, lines 3-7 and 14-15, and page 19, lines 1-3). In support, the Examiner pointed to a paragraph in Segal, the relevant section of which states that, "*Inherently, these computerized records are more organized, accurate, and accessible in comparison to paper-based records.*" (Segal, Paragraph 0008). As best Appellant can determine, the Examiner assumes that a desire for accuracy of medical records is equivalent to the positive elements of nonrepudiation and certification as claimed by Appellant. This is baseless. The Examiner is arbitrarily construing claim terms by departing from the claims in Segal, essentially fabricating new claim elements from whole cloth.

Whether accuracy of medical records is a goal in the art has nothing to do with achieving that goal, and nothing to do with nonrepudiation or certification of medical records. It is well established that a claim term is read in context with the claims themselves and also in context with the specification (*Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 (Fed. Cir. 1998, *affirmed in Phillips v. AWH Corp.* (Federal Circuit Docket No. 03-1269, Opinion of July 12, 2005). The Examiner failed to perform the proper analysis and, besides ignoring context, the Examiner's assumptions require hindsight, which is impermissible in analyzing questions of prior art. Appellant's claim terms are clear to those skilled in the art and the specification provides consistent guidance. Analyzing the claims makes clear that neither certification nor nonrepudiation is disclosed or suggested in Segal.

For at least these reasons, Appellant respectfully requests that all rejections based on Segal be withdrawn for failure to disclose Appellant's claimed invention and for failure to establish a *prima facie* case of obviousness.

4) The Affidavit Sufficiently Describes Appellant's Invention

Appellant respectfully asserts that the instant claims are fully disclosed in and supported by the Affidavit sufficiently to swear behind Segal. However, in the Office Action, the Examiner stated that she was unable to locate "the invention of the claims" within the Affidavit (final Office Action, page 15). This is also clear error because, as is clear to one skilled in the art, the entirety of the Affidavit evidence is directed to Appellant's invention.

For reasons that are at best unclear, the Examiner chose to ignore all disclosures of the claimed invention in the Affidavit (MPEP § 715.02: "*[A]n affidavit is not insufficient merely*

because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient...."). Instead, the Examiner focuses her review on disclosures in the Affidavit that are allegedly *absent* from Applicant's claims. As stated by the Examiner:

> [T]o the extent the Examiner understands the submitted materials, the product description of the PatientDirect system (which appears to be the closest item to the subject of the present invention) given at page 4 of the "Executive Summary" document makes reference to elements not present in any of the recited claims, namely, an "Internet document transmission service," a "second opinion/discount broker strategy," and an XML/HTTP protocol with encryption." (punctuation corrected by Appellant)

To review Applicant's Affidavit for an unclaimed invention is neither relevant nor material. The Examiner's duty is to review the Affidavit for the claimed invention, and her failure to do so is clear error. Further, in her attempt to highlight this purported deficiency, the Examiner actually cited to highly relevant portions of the Affidavit. For example:

As is clear to those of ordinary skill in the art, "XML/HTTP protocol" with encryption is typical of secure communications over the Internet. This is the essence of a "broad-band, computer-based networked system" as set forth in the preamble to claim 1.

Again as is clear to those skilled in the art, applicant's claimed invention directly involves "document transmission" over the Internet (see claim 4).

On its face, Applicant's claimed invention, including aspects improperly re-interpreted by the Examiner, is encompassed within the Affidavit sufficiently to swear behind Segal. No more is required of Applicant; Segal must be removed as a prior art reference.

5) All Aspects of the Examiner's Prior Art Analysis are Error

To establish *prima facie* obviousness, the Examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*See, e.g., In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *In re Merck & Co., Inc.,* 800 F.2d 1091 (Fed. Cir. 1986); *In re Royka,* 490 F.2d 981 (CCPA 1974)). Most inventions arise from a combination of old elements, and each element may often be found in the prior art (*In re*

Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998)). However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole (*Id.* at 1355, 1357). Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention (*Id.*). In practice, this requires that the Examiner "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious" (*Id.* at 1357-59). This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test. The Examiner has failed in this regard.

In view of the above, Appellant respectfully asserts that the Examiner's rejection is based on an "obvious to try" standard rather than the requisite *Graham* factors. The cited art provides no indication of which parameters are critical and provides no direction as to which combination and/or modification of parameters is likely to be successful (*See e.g.*, *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Indeed, the cited art specifically teaches away from Appellant's invention. The entirety of the Examiner's prior art analysis is error, and should be rejected.

C. The Examiner's Mutually Exclusive Interpretations of "Accuracy" in Relation to "Certification" and "Non-Repudiation" Require, Inevitably, that Appellant's Claims Be Granted.

The Examiner created a conundrum for herself by using mutually inconsistent definitions of the word "accuracy" as the basis for (1) rejecting certain of Appellant's claims involving "certification" and "nonrepudiation" (for this purpose the Examiner defined "certification" and "nonrepudiation" as meaning "accuracy") while (2) rejecting the Appellants § 1.131 Affidavit, swearing behind Segal, because "accuracy" in the Affidavit did not, according to the Examiner, mean "certification" or "nonrepudiation."

At this stage of the proceedings, use of either interpretation will result in a grant. This is so because either (1) the asserted prior art is irrelevant to "certification" and "nonrepudiation", or (2) if the asserted prior art is relevant to "certification" and "nonrepudiation" because "accuracy means ""certification" and "nonrepudiation," then Appellant has demonstrated in its Affidavit that its invention included "accuracy" prior to the date of the asserted prior art.

III. Rejection of Claims 13-15, 20-29, 32-33 and 48-50 Under 35 U.S.C. § 103(a) in View of Malik is Erroneous

A. Errors in the Examiner's Analysis of Appellant's § 1.131 Affidavit Demonstrate That the Rejections Based on Asserted Prior Art Must Be Withdrawn.

The Examiner committed at least two clear errors in rejecting Appellant's §.1.131 Affidavit. First, she erroneously required that there be a "nexus" between the Affidavit and the claimed invention (final Office Action, page 15). Second, she erroneously required that "the whole invention claimed or something falling within the claim" be located within the Affidavit (final Office Action, page 15).

As to the first error, there is no "nexus" requirement in 37 CFR §.1.131. Rather, the requirement for a "nexus" is found in §.1.132. This was repeatedly noted to the Examiner, yet the Examiner repeatedly asserted, without further comment, that Appellant's Affidavit fails because there is no "nexus" between the Affidavit and the instant claims (final Office Action, page 15).

Section 1.132 contains an explicit textual requirement for a "nexus" and §.1.131 does not. This textual difference precludes the Examiner from imposing a requirement for a nexus in § 1.131, as she has done. The omission of a "nexus" requirement in § 1.131, followed by the explicit textual inclusion of a "nexus" requirement in the very next section, § 1.132, in fact *requires* the Examiner to draw the negative inference that § 1.131 does not have a "nexus" requirement, and to recognize that "nexus" cannot be read into § 1.131 by implication or any other means. This analysis follows established rules of textual interpretation as described above.

The Examiner's second error evinces an inexplicable disregard of the clear text of the MPEP § 715.02, because the Examiner erroneously asserts that Appellant must state the entirety of its claimed invention in the Affidavit in order for her to consider the Affidavit sufficient (final Office Action, page 15). This directly contravenes MPEP § 715.02, which states that Appellant *only* needs to show that the Affidavit contains *the elements of the claimed invention that are found in the supposed prior art:*

> [A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. *If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown*

in the reference or activity, the affidavit or declaration is sufficient....(Emphasis added.)

The Examiner's analytical approach to Appellant's Affidavit is contrary to the MPEP, and thus clear error. Malik should be removed as prior art references in view of Appellant's Affidavit. Further, because the Examiner provided no comments regarding Malik and Appellant's Affidavit, Malik at least should be removed as a prior art reference and all claims rejected over Malik be declared allowable.

Moreover, Appellant respectfully asserts that the Examiner failed properly to examine the Affidavit as she is required to do under M.P.E.P. 715. Appellant's Affidavit includes evidence establishing conception and reduction to practice of Appellant's claimed invention sufficiently to overcome Malik as prior art. That evidence was initially provided on July 7, 2005, with the most relevant sections highlighted as a courtesy for the Examiner. Unfortunately the highlighting was lost when the Affidavit was processed by the PTO into electronic form, which is how it was received by the Examiner. Thus, what the Examiner received was not what Appellant filed, but an incomplete copy. This was an error by the PTO, but one which was readily apparent to the Examiner. The error could have been rectified had the Examiner simply telephoned the undersigned. It is not Appellant's duty to highlight the Affidavit evidence. The burden properly to examine the Affidavit lies with the PTO, not with the Appellant. It was neither unreasonable nor burdensome for the Examiner to review the Affidavit, and her failure to do so is clear error.

B. Errors in Examining Appellant's Claims of "Certification" and "Non-Repudiation," Particularly a Teaching Away, Show Hindsight and Violation of the MPEP, So That Rejections for Failure to Disclose the Claimed Invention and for Obviousness Must Be Withdrawn.

1) The Claim Element of "Nonrepudiation"

Nonrepudiation is positively recited as an element of Appellant's claimed invention (e.g., claims 25 and 26). As recited in claim 1, medical information contained within medical records is verified as accurate and correct such that: "*one or more records of the collection possess a characteristic of nonrepudiation.*" This element is also clear from the specification: *"Medical records that are verified as accurate attain the aspect of nonrepudiation (i.e. that the accuracy and correctness of the information [in the medical record] is as good or better than exists at the source from which the records were obtained) and may for all purposes be relied upon"*

(specification, page 17, lines 14-17). This claim element of Appellant's invention is nowhere to be found in Malik.

In a preferred embodiment (e.g., claims 23 and 24), nonrepudiation is attained from an accurate medical record that is then subjected to a separate additional step of verification or vetting (*also see* specification, page 17, lines 11-21). Therefore, as is unambiguously set forth in one embodiment, accuracy alone does not create the element of nonrepudiation. For at least this reason, nonrepudiation is not disclosed or suggested in Malik.

2) The Claim Element of "Certification"

Certification is positively recited as an element of Appellant's claimed invention. (e.g., claims 21 and 22). As recited in claim 10, the invention comprises a collection of medical records wherein "*each medical record is certified as accurate.*" As stated by Appellant: "*The invention may include a form of medical record that can be completed at one of a plurality of certification levels*" (specification, page 15, lines 12-13). "*Certification levels refer to standards of verification such as, for example, 'initial' being self-certification wherein the member certifies that the record is correct, 'basic' whereby the system provider certifies that the record is complete for all information gathered ....*" (specification, page 15, lines 22-25; and claims 20, 37, 43).

3) Malik Does Not Disclose or Suggest the Claimed Invention

Malik fails to disclose or suggest at least the elements of "certification of medical records" (claims 21 and 22) or "nonrepudiation of medical records" (claims 25 and 26) as these elements are claimed by Appellant. The Examiner's re-interpretation of these elements is based on a Procrustean distortion of claim terms for the obvious purpose of shoe-horning these elements into portions of Malik. This is purposeful, and obvious, hindsight.

As best Appellant can determine, the Examiner assumes that a desire for accuracy of medical records is equivalent to the positive elements of nonrepudiation and certification as claimed by Appellant. This is baseless. The Examiner is arbitrarily construing claim terms by departing from the claims in Malik, essentially fabricating new claim elements from whole cloth.

Whether accuracy of medical records is a goal in the art has nothing to do with achieving that goal, and nothing to do with nonrepudiation or certification of medical records. It is well

established that a claim term is read in context with the claims themselves and also in context with the specification (*Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473 (Fed. Cir. 1998, *affirmed in Phillips v. AWH Corp.* (Federal Circuit Docket No. 03-1269, Opinion of July 12, 2005). The Examiner failed to perform the proper analysis and, besides ignoring context, the Examiner's assumptions require hindsight, which is impermissible in analyzing questions of prior art. Appellant's claim terms are clear to those skilled in the art and the specification provides consistent guidance. Analyzing the claims makes clear that neither certification nor nonrepudiation is disclosed or suggested in Malik.

For at least these reasons, Appellant respectfully requests that all rejections based on Malik be withdrawn for failure to disclose Appellant's claimed invention and for failure to establish a *prima facie* case of obviousness.

4) The Affidavit Sufficiently Describes Appellant's Invention

Appellant respectfully asserts that the instant claims are fully disclosed in and supported by the Affidavit sufficiently to swear behind Malik. However, in the Office Action, the Examiner stated that she was unable to locate "the invention of the claims" within the Affidavit (final Office Action, page 15). This is also clear error because, as is clear to one skilled in the art, the entirety of the Affidavit evidence is directed to Appellant's invention.

For reasons that are at best unclear, the Examiner chose to ignore all disclosures of the claimed invention in the Affidavit (MPEP § 715.02: "*[A]n affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the activity relied upon. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient....*"). Instead, she focuses her review on disclosures in the Affidavit that are allegedly *absent* from Applicant's claims. As stated by the Examiner:

> [T]o the extent the Examiner understands the submitted materials, the product description of the PatientDirect system (which appears to be the closest item to the subject of the present invention) given at page 4 of the "Executive Summary" document makes reference to elements not present in any of the recited claims, namely, an "Internet document transmission service," a "second opinion/discount broker strategy," and an XML/HTTP protocol with encryption." (punctuation corrected by Appellant)

To review Applicant's Affidavit for an unclaimed invention is neither relevant nor material. The Examiner's duty is to review the Affidavit for the claimed invention, and her failure to do so is clear error. Further, in her attempt to highlight this purported deficiency, the Examiner actually cited to highly relevant portions of the Affidavit. For example:

As is clear to those of ordinary skill in the art, "XML/HTTP protocol" with encryption is typical of secure communications over the Internet. This is the essence of a "broad-band, computer-based networked system" as set forth in the preamble to claim 1.

Again as is clear to those skilled in the art, applicant's claimed invention directly involves "document transmission" over the Internet (see claim 4).

On its face, Applicant's claimed invention, including aspects improperly re-interpreted by the Examiner, is encompassed within the Affidavit sufficiently to swear behind Malik. No more is required of Applicant; Malik must be removed as prior art references.

5) All Aspects of the Examiner's Prior Art Analysis are Error

To establish *prima facie* obviousness, the Examiner must show in the prior art some suggestion or motivation to make the claimed invention, a reasonable expectation for success in doing so, and a teaching or suggestion of each claim element (*See, e.g., In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *In re Merck & Co., Inc.,* 800 F.2d 1091 (Fed. Cir. 1986); *In re Royka,* 490 F.2d 981 (CCPA 1974)). Most inventions arise from a combination of old elements, and each element may often be found in the prior art (*In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998)). However, mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole (*Id.* at 1355, 1357). Rather, to establish a *prima facie* case of obviousness based on a combination of elements disclosed in the prior art, the Examiner must articulate the basis on which it concludes that it would have been obvious to make the claimed invention (*Id.*). In practice, this requires that the Examiner "explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious" (*Id.* at 1357-59). This entails consideration of both the "scope and content of the prior art" and "level of ordinary skill in the pertinent art" aspects of the *Graham* test. The Examiner has failed in this regard.

In view of the above, Appellant respectfully asserts that the Examiner's rejection is based on an "obvious to try" standard rather than the requisite *Graham* factors. The cited art provides no indication of which parameters are critical and provides no direction as to which combination and/or modification of parameters is likely to be successful (*See e.g.*, *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). Indeed, the cited art specifically teaches away from Appellant's invention. The entirety of the Examiner's prior art analysis is error, and should be rejected.

C. The Examiner's Mutually Exclusive Interpretations of "Accuracy" in Relation to "Certification" and "Non-Repudiation" Require, Inevitably, that Appellant's Claims be Granted.

The Examiner created a conundrum for herself by using mutually inconsistent definitions of the word "accuracy" as the basis for (1) rejecting certain of Appellant's claims involving "certification" and "nonrepudiation" (for this purpose the Examiner defined "certification" and "nonrepudiation" as meaning "accuracy") while (2) rejecting the Appellants § 1.131 Affidavit, swearing behind Malik, because "accuracy" in the Affidavit did not, according to the Examiner, mean "certification" or "nonrepudiation."

At this stage of the proceedings, use of either interpretation will result in a grant. This is so because either (1) the asserted prior art is irrelevant to "certification" and "nonrepudiation", or (2) if the asserted prior art is relevant to "certification" and "nonrepudiation" because "accuracy means ""certification" and "nonrepudiation," then Appellant has demonstrated in its Affidavit that its invention included "accuracy" prior to the date of the asserted prior art.

Conclusion

Appellant respectfully submits that the present application is in condition for allowance, which action is courteously requested. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 14.1437. Please credit any excess fees to such account.

Respectfully submitted,
NOVAK DRUCE & QUIGG LLP

Date: October 12, 2006

By: _____
James Remenick
Registration No. 36,902

Customer No. 28694
Novak, Druce & Quigg LLP
1300 Eye Street, N.W.
400 East Tower
Washington, DC 20005
Telephone: (202) 659-0100
Facsimile: (202) 659-0105

CLAIMS APPENDIX

Claim 1. (previously presented) A broad-band, computer-based networked system comprising:

a collection of patient-based electronic medical records containing medical information of a plurality of persons, wherein:

the medical records are obtained and electronically compiled from a plurality of sources;

one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct;

the medical record of a person is transmissible in whole or in part only to that person and others authorized by that person;

each medical record can be supplemented with additional information; and

additional medical records for additional persons may be added to the collection;

a secure access for allowing each person to access only their own medical record; and

at least another secure access for allowing said others authorized to access only that person's medical record.

Claim 2. (previously presented) The system of claim 1, wherein said medical records are electronically complied by direct input or digital scanning of written information into a computer-readable format.

Claim 3. (original) The system of claim 1, wherein the sources are selected from the group consisting of hospitals, clinics, physician's offices, pharmacies and combinations thereof.

Claim 4. (original) The system of claim 1, wherein said medical records are transmissible through the Internet.

Claim 5. (original) The system of claim 1, wherein the medical record for each person contains one or more of: a table of contents, an index, a source notation for information contained within the medical record, an electronic search tool, annotations for errors, linked annotations for errors, treatment options, health care choices, verification standards and news items relevant to the information in the medical record.

Claim 6. (original) The system of claim 1, wherein the secure access and the another secure access comprise passwords or encryption keys.

Claim 7. (original) The system of claim 1, wherein the others authorized are selected from the group consisting of physicians, nurses, hospitals and health care institutions.

Claim 8. (previously presented) The system of claim 1, wherein all of the medical records of the collection possess the characteristic of non-repudiation.

Claim 9. (previously presented) The system of claim 1, wherein said non-repudiated medical record is primary for treatment of a person to whom said non-repudiated medical record pertains.

Claim 10. (original) The system of claim 1, wherein each medical record is certified as accurate.

Claim 11. (previously presented) The system of claim 1, wherein the medical information of each certified medical record is certified by a person to whom the medical record pertains, by

the source from which said each medical record was obtained, by a system provider or by a combination thereof.

Claim 12. (original) The system of claim 1, wherein the collection comprises medical records of more than 100,000 persons.

Claim 13. (original) The system of claim 1, wherein said collection complies with a federal or state standard of privacy and security.

Claim 14. (original) The system of claim 13, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.

Claim 15. (original) The system of claim 13, wherein said collection complies with all state standards of privacy and security for the geographical area in which the system operates.

Claim 16. (original) The system of claim 1, further comprising a fee which is assessed for each access to a medical record.

Claim 17. (original) The system of claim 1, further comprising a fee which is assessed for maintenance of a medical record.

Claim 18. (previously presented) The system of claim 1, wherein the medical information of at least one medical record is vetted.

Claim 19. (previously presented) The system of claim 18, wherein the medical information of the vetted medical record contains one or more of: corrections of incorrect information, notations of incorrect information, notations of anomalies, linking of errors, linking of anomalies, notation of discrepancies, linking of discrepancies, and combinations thereof.

Claim 20. (previously presented) A broad-band, computer-based networked system for individual control and management of electronic medical records comprising

a plurality of medical records representing a plurality of persons wherein

said plurality of medical records complies with a federal standard of privacy and security and

the medical information of at least one medical record of the plurality has been vetted, such that the medical information of said at least one medical record is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation.

Claim 21. (original) The system of claim 20, which allows for certification of said medical records.

Claim 22. (original) The system of claim 21, wherein certification represents a predetermined degree of completeness, accuracy or both to said medical records.

Claim 23. (previously presented) The system of claim 20, which allows for vetting of the medical information of said medical records.

Claim 24. (original) The system of claim 23, wherein vetted medical records have been reviewed and corrected or annotated for errors, discrepancies and anomalies.

Claim 25. (previously presented) The system of claim 20, which allows for non-repudiation of the medical information of said medical records.

Claim 26. (previously presented) The system of claim 25, wherein non-repudiated medical records are primary for treatment of the person to whom each medical record pertains by health care providers.

Claim 27. (previously presented) The system of claim 20, wherein the plurality of medical records complies with the Health Insurance Portability and Accountability Act of 1996.

Claim 28. (previously presented) The system of claim 27, which further complies with a state standard of privacy and security.

Claim 29. (original) The system of claim 20, wherein access to any one medical record is restricted to the person to whom said one medical record pertains or to others designated and authorized by said person.

Claim 30. (previously presented) A method for creating an accessible electronic medical records database comprising:

obtaining and compiling a medical record pertaining to a patient;

determining accuracy and correctness of medical information within each medical record;

electronically inputting said medical information within each medical record into a secure computer database containing other medical records; and

allowing said patient and those authorized by said patient access to said patient's medical record wherein access to all other medical records is blocked.

Claim 31. (previously presented) The method of claim 30, wherein determining accuracy and correctness comprises vetting, identifying or linking errors or inconsistent information, or expunging clear errors in input.

Claim 32. (original) The method of claim 30, wherein access to the electronic medical record database complies with a federal standard of privacy and security.

Claim 33. (original) The method of claim 30, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.

Claim 34. (original) The method of claim 30, further comprising updating the medical record database with additional medical information pertaining to said patient.

Claim 35. (original) The method of claim 30, further comprising securely transmitting all or part of said patient's medical record to a third party as designated by said patient.

Claim 36. (original) The method of claim 30, further comprising displaying said medical record pertaining to a patient.

Claim 37. (previously presented) An electronic database of medical records created and compiled according to the method of claim 30, wherein the medical information contained within

said medical records is more accurate and correct as compared to those sources from which the medical records were obtained.

Claim 38. (original) The database of claim 37, which contains the entire medical history of at least one person.

Claim 39. (original) The database of claim 37, wherein each medical record is remotely accessible in whole or in part only by the patient to whom the medical record pertains and those authorized by said patient.

Claim 40. (previously presented) A business model comprising:

operating and maintaining a secure database of medical records containing medical information of many persons obtained from a plurality of sources;

whereby each medical record is accessible through transmission pathways and only by the person to whom the medical record pertains and those authorized by said person; and

accuracy and correctness of the medical information within at least one medical record is determined to be as good or better than exists at the source from which said at least one medical record was obtained.

Claim 41. (previously presented) A method for integrating medical records to create a certified medical record database comprising:

obtaining medical information from one or more healthcare sources for a plurality of patients;

electronically inputting all of the medical information obtained into a secure computer database to create medical records; and

certifying that each of said medical records meet one of a plurality of certification standards established by a service provider to create the certified medical record database.

Claim 42. (original) The method of claim 41, wherein any one of the certified medical records can be transmitted only to the patient to whom the record pertains or those authorized by said patient.

Claim 43. (original) The method of claim 41, wherein the plurality of certification standards are selected from the group consisting of self-certification, certification by the service provider and combinations thereof.

Claim 44. (original) The method of claim 41, further comprising a step whereby said patient obtains an analysis of the medical record.

Claim 45. (original) The method of claim 41, further comprising providing said certified medical record database with the characteristic of non-repudiation.

Claim 46. (previously presented) A computer system for management of patient-based medical records comprising:

a database of medical records pertaining to one or more subjects;

a receiver for receiving the medical information pertaining to said medical records from one or more senders;

a process for verifying that the medical information received is accurate and correct by at least vetting said medical information;

a process for authorizing said senders and said additional receivers according to a set of rules; and

a transmitter for transmitting at least a portion of said medical records to one or more additional receivers; and

authorization for authorizing said senders and receivers according to a set of rules.

Claim 47. (original) The computer system of claim 46, wherein said database is a secure database.

Claim 48. (original) The computer system of claim 47, wherein said secure database complies with a federal standard of privacy and security.

Claim 49. (original) The computer system of claim 48, wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.

Claim 50. (original) The computer system of claim 48, which further complies with a state standard of privacy and security.

Claim 51. (previously presented) The computer system of claim 46, wherein said receiver is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server.

Claim 52. (previously presented) The computer system of claim 46, wherein said transmitter is selected from the group consisting of: modem, cellular transmitter, infrared transmitter, Ethernet card, facsimile, cable modem, satellite transmitter, analog transmitter, Internet hub, and web-server.

Claim 53. (previously presented) The computer system of claim 46, wherein said process of authorizing comprises public key encryption, digital signatures, biometrics, certificate authorities, or user passwords.

Claim 54. (original) The computer system of claim 46, wherein said portion of said medical records have the characteristic of non-repudiation.

Claim 55. (previously presented) The computer system of claim 46, wherein said non-repudiated medical records of said one or more subjects are primary for treatment of said one or more subjects by health care providers not involved with creating said medical information.

Claim 56. (previously presented) The computer system of claim 46, further comprising an integrator for reception, display, analysis and modification of said medical records available to be performed on a plurality of systems of health care providers, payors, clearinghouses, or oversight agencies.

Claim 57. (original) The computer system of claim 46, wherein said database is administered by a service provider other than said subjects, senders, and receivers.

Claim 58. (previously presented) The computer system of claim 46, further including vetting that allows said subjects to supplement said medical records with information relating to the accuracy of said medical records.

Claim 59. (previously presented) The computer system of claim 46, wherein said medical records are owned and controlled by said subjects.

EVIDENCE APPENDIX

Copies of the Rule 131 Affidavits submitted on July 7, 2005 are attached hereto.

PATENT
New Attorney Docket No. 144009.00100
Old Attorney Docket No. 031672.0005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Wm.A. Knaus & R.D. Marks	)
U.S. Appl. No.:	09/822,261	) Group Art Unit: 3636
Filing Date:	April 2, 2001	) Examiner: Lena Najarian
Title:	BROADBAND COMPUTER-BASED NETWORKED SYSTEMS FOR CONTROL AND MANAGEMENT OF MEDICAL RECORDS	

MAIL STOP - AMENDMENT

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

DECLARATION UNDER 37 C.F.R. §1.131

We, William A. Knaus with a residence address at 1929 Lewis Mountain Road, Charlottesville, VA 22903, and Richard D. Marks with a residence at 6004 Balsam Drive, McLean, VA 22101, are co-inventors of the invention disclosed and claimed in the above-captioned patent application.

Prior to February 9, 2000, we conceived and reduced to practice the systems and methods according to the claims of the instant patent application, at least to the extent that such systems and methods are disclosed in U.S. Patent Application No. 09/838,878 (Segal), U.S. Provisional Application No. 60/181,215 (the Segal Provisional), U.S. Patent Application No. 09/776,673 (Malik), and U.S. Provisional Application No. 60/60/200,091 (the Malik Provisional) (collectively the "Cited References"), as disclosed in the attached documents. Sections of the attached documents are highlighted to emphasize aspects of the instant invention that were alleged to be

disclosed in these Cited References. Accordingly, Segal, Malik, the Segal Provisional and the Malik Provisional cannot be considered to be prior art to our claimed invention.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

_____ Date: July 7, 2005

Name: William A. Knaus

 Date: July 7, 2005

Name: Richard D. Marks

Attached: Exhibit A

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William A. Knaus Date: July 7, 2005

Name: William A. Knaus

_____ Date: July 7, 2005

Name: Richard D. Marks

Attached: Exhibit A

PatientDirect Systems

Executive Summary

Company Description

PatientDirect provides online individual medical record collection and interpretation services- a market estimated to be $XX billion within five years. PatientDirect enables individuals to CONTROL-- obtain, update, store, and distribute—all their medical record data (including testing and imaging results). Through unique decision support components the individual will also obtain UNDERSTANDING of the meaning of their data for all aspects of their care. PatientDirect's mission is to become the trusted agent and leading provider of individual medical record services for all consumer-to-provider transactions within the entire medical service industry.

A

PatientDirect will take advantage of the following to achieve market dominance; (1) the rise in popularity of the Internet for consumer information exchange and the associated technical infrastructure that enables the efficient and secured transfer of data, (2) the emerging Health Care Portability and Privacy Act (HIPPA) regulations that will require increased reliance on electronic transfer of medical records in all medical settings and will grant individuals explicit right of access to their medical records data and an implied license to author a unique compilation of these data, (3) the growing need and empowerment of consumers to monitor the safety and appropriateness of healthcare decision making for both their personal and family members' care, and (4) the involvement of accomplished developers and strategic investors and marketing and strategic alliances that will enable the company to capture market share rapidly.

Our unique approach integrates medical record keeping and decision support into a transaction-based service in which we charge for record interpretation and transmission and give-away the enabling software. PatientDirect gains immediate access to a large targeted customer base while our alliance partners gain product benefits and an additional revenue stream.

B

We have created PatientDirect's business model, internal structure, and controls to minimize time and cost in executing our plan. ***More to come describing key partners***

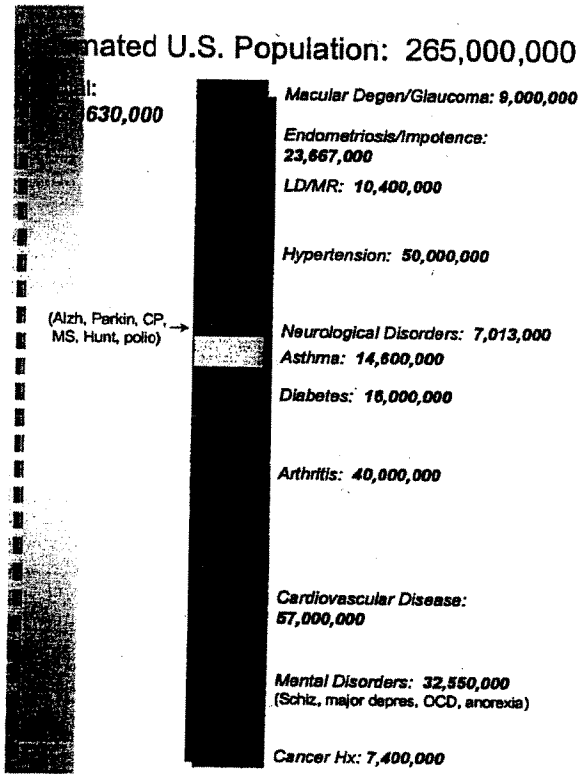
C

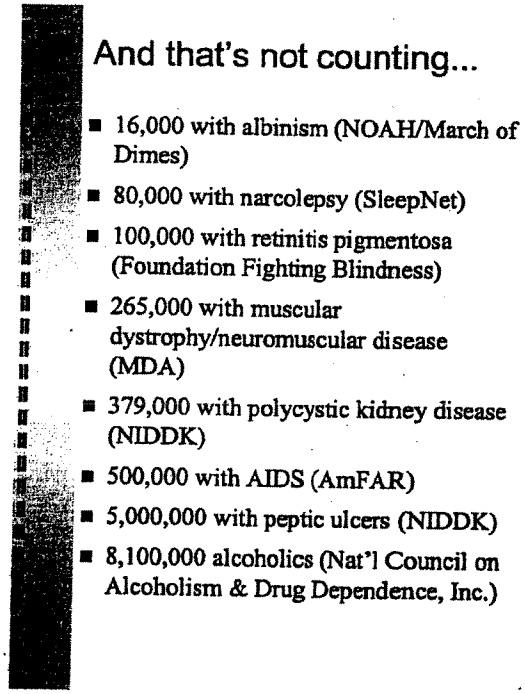
The Opportunity

In 1998, US healthcare was a $1.1 trillion industry. It is expected to grow to $2.1 trillion in 2007. The healthcare industry, especially the clinical component, is substantially behind other service industries in its use of information technology. (only financial and administrative data in healthcare have been automated with 80% of hospital, 40 % physician claims and less than 10% of clinical encounters supported by EDI) The physician or ambulatory office encounter market (where PatientDirect will initially focus activities) is particularly behind in automation. It recorded 788 million encounters in 1998 and $230 billion in charges. (An average of 60% of this total is spent on overhead, especially record storage and retrieval, the highest overhead percentage of any service industry.) This market will grow by 10 percent annually and will inevitably move from paper to electronic storage and delivery as demands for quality and efficiency increase, and government regulations force encryption and electronic authorization of individual

medical record transmittals. It is estimated that by 2005, over one-third of all medical record transfers, or about $XX billion of the expected $XX billion market will be over the Internet.

Marketing Strategy
Our first market for PatientDirect is on individuals who require complex and/or ongoing medical services from a variety of providers, "the chronically ill". This market is particularly attractive due to the large and growing number of such individuals within the US population. Indeed, individual estimates of the prevalence of chronic conditions exceed the current U.S. population (See Figure). The Robert Wood Johnson Foundation estimates that up to 90 million Americans have one or more of these conditions with sufficient severity to obtain office based consultations an average of 6 times annually- twice the national average of 3.





Many of these individuals and their family members are closely involved and concerned with the quality of their care. (For patients over age 65, 55% are estimated to have a chronic condition and 80% of these individuals are involved in their care) PatientDirect bridges the gap for these individuals between the office-based providers that lack electronic medical record storage and decision support systems and the fragmented Healthcare IT industry which has been slow to react to Internet possibilities and

continues to attempt integration from a provider, system, or enterprise viewpoint not from a consumer perspective. As a result of this situation, the individual seeking health care today has the following questions and issues:

-Is the advice I'm getting good?
-What doctor is the best one to see for this condition?
-Does this doctor know all about my medical history?
-Will the drugs just prescribed interfere with my existing medications?
-Do they know I had a bad reaction to sulfa drugs when I was young?
-What is going to happen if I have the operation?
-What are my choices and how do they compare?
-Am I likely to need nursing home care?
-What does this new lab result mean for my chance of recovery?
-Is this service covered by insurance?

The following are also current concerns that have been prompted by widely disseminated media reports on the current state of medical record keeping. Their visibility will be raised and encouraged by HIPPA

-Who has copies of my medical record?
-Does the specialist have my latest EKG tracing?
-Did my records go to the right clinic?
-Did anyone besides the doctor look at it?
-Did I receive notification that my doctor sent my records to the hospital?

Various consumers care about particular aspects of these issues. Our first market for PatientDirect will be consumers that, because, of the burden of complex disease are heavily invested in negotiating the best care from multiple providers.

PatientDirect believes that alliance partnerships are an efficient and economical way to capture market share rapidly. We gain distribution outlets and cooperative marketing arrangements through application vendors who embed our API in their software. PatientDirect is currently investigating relationships with major national online vendors such as AOL and YAHOO to offer PatientDirect services to their online customer base. We are also approaching more specialized software vendors—such as DXPLAIN and medication interaction screening software-- that have traditionally offered their interpretive and decision support approaches for medical data to providers—to offer these services directly to consumers using PatientDirect as the source of medical record data.

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Because of the tremendous potential of this new market, competition does exist. All of the major healthcare IT vendors are developing Internet enabled applications. Cerner Corporation, for example, became a major development partner in Careinsite. MedicaLogic also aims to automate the physician's office and distribute an individual medical record. There are also specialty disease management offerings that are web-based (ProMedex;LifeMasters).LifeMasters recently signed a joint marketing agreement with iVillage to be the online's network exclusive provider of specific personalized

health management tools. Start-ups-MedicalRecord.com aim at assisting the consumer in compiling an online medical record. Large emerging Internet based healthcare portals like Dr.Koop.com are also promising to have online medical records controlled by the patient.

Product Description

PatientDirect is a consumer support and consumer-to-medical system Internet document transmission service that offers an integrated and secure method of controlling and interpreting medical record data. We use a second opinion/discount broker strategy in which to derive revenues-and high margin earnings-from selling clinical decision support and document transaction-certification authority that are accessed through free software that maintains and protects all the individual's medical records.

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Our customer-focused approach dictates that this service be available from browsers as well as desktops and enterprise applications. Our API allows our alliance partners the ability to offer-and earns commissions on certain "PatientDirect enabled"-decision support and record transmission services. In all marketing efforts, however, independence of the system from any provider or healthplan and strict confidentiality regarding the data will be stressed.

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PatientDirect service uses an XML/HTTP protocol with encryption. SSL is also used as needed for the browser-based version of the product. Our algorithms and other methods of interpreting medical record data are unique and we are investigating patent opportunities. We will also expect to be involved in efforts to create an Extensible Markup Language (XML) data exchange standard for the medical sector. This standard and others like it will lower our integration costs while helping to solidify our position in the medical marketplace.

C

Management Team & Advisors

The founders and developers of APACHE Medical Systems Inc. designed PatientDirect, along with key outside advisors skilled in the healthcare information technology industry.
Details to follow
APACHE Medical Systems Inc. (AMSI-NASDAQ), a Delaware corporation based in McLean, Virginia , is the recognized leader in the delivery of electronic clinical decision support systems, strategic and clinical consulting services for the care of high-risk, high-cost patients. AMSI's products and services enables health systems, hospitals and providers to apply an evidence-based approach to achieve clinical performance excellence, substantially reduce cost, and compete effectively under managed care. AMSI's Voyager and Discover electronic decision support systems enable it's customers to comprehensively evaluate and interpret their utilization and outcome from critical care services retrospectively, prospectively, and in real time at the bedside for decisions on individual patients, the only clinical decision support system to provide such capability. APACHE is recognized within the medical community as a "gold standard" medical information source. PatientDirect will become the gold standard for consumers.

AMSI is currently migrating existing critical care applications to the Internet. It is also implementing an application of an electronic based second opinion capability-a decision

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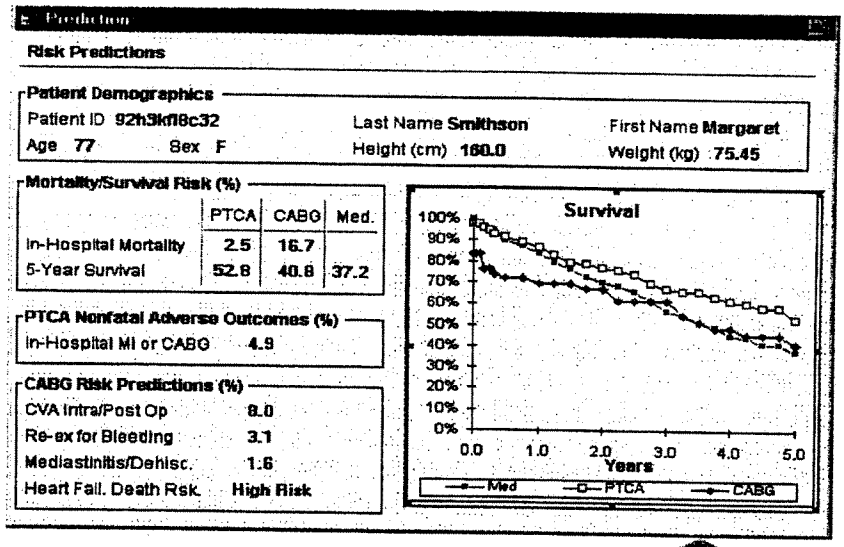
support for ambulatory patients with cardiovascular disease who are facing the alternatives of surgery, angioplasty, or medical management. This illustrates the type and function of decision support tools possible for implementation in PatientDirect.

APACHE CV Risk Predictor



AMcCoy/COMPANY CONFIDENTIAL

APACHE Medical Systems, Inc.

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The principals of PatientDirect have also developed the working prototype of a family history data collection tool that has interpretive capabilities. Termed HealthHeritage it illustrates another of the possible components that will be included in a comprehensive PatientDirect application.

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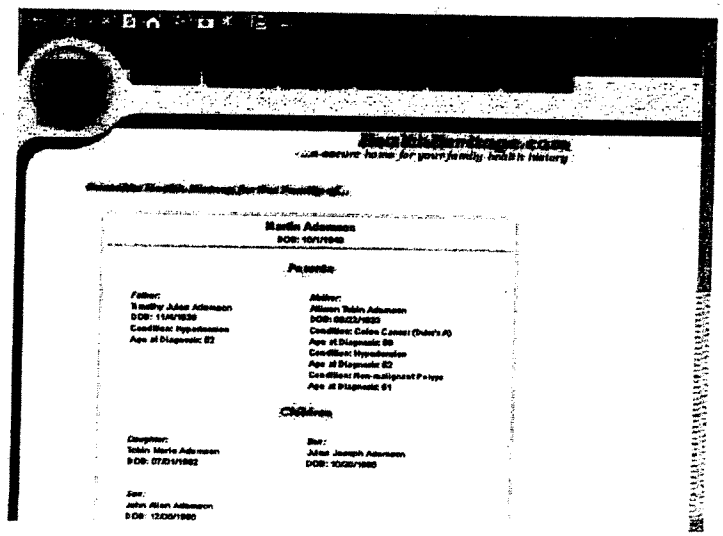

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Financial Summary

From incorporation to the formation of PatientDirect, PatientDirect has been financed through founder stock and seed capital from ***details to come.*** We are raising $20 Million in two rounds----$5 million to officially launch the service (from AMS? others?) and an additional $15 million by end 2000-early 2001 to expand the company and enable us to achieve profitability by the second quarter 2002. The company's financial projections are based on conservative assumptions of Internet usage, growth of electronic medical encounters on the Internet, and number of users benefiting from PatientDirect. Based on these assumptions, PatientDirect will achieve revenues of $XX.X million and net income of $XX>X million in 2005.

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PatientDirect has been designed as a company that can generate earnings as well as produce great investment returns. The plan has been designed with at least two potential liquidity events. In the event current Internet valuations continue we could provide liquidity in the form of? reverse merger with AMSI ? Alternatively we expect consolidation as key health care portals emerge as preferred entry points. The winning players will turn to more sophisticated service, content, and care offerings to maintain and expand their user base. Production of the type of sophisticated proprietary intellectual content PatientDirect is not the focus of current healthcare portals.

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PatientDirect Systems

The Online Individual Medical Record Industry

PatientDirect is the process of presenting a comprehensive compilation of an individual's medical record for direct delivery to individuals, providers, and other authorized users desktops over either the Internet or a private network. Individuals can examine their records, update information, and authorize transfer of data with a few mouse clicks.

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Entities in the Online Medical Record Cycle

There are at least three distinct parties involved in the medical record collection and interpretation process.

Consumers-Lack of Trusted Agent/Concerns with Safety

Any individual that receives medical services on an ongoing basis is defined as an end-user of this technology. At the level of the household, individuals are now seeking assistance from medical service providers an average of 3.0 times per year. There are more than 90 million US adults who are defined as "high-users" of medical care services with approximately 6 medical primarily ambulatory encounters per user per year. These patients want to better educate, empower, and protect themselves. A 1998 American Hospital Association focus group of consumers with substantial exposure to the health care system revealed that there is a consistent feeling that no one in the is on their side.

Financial considerations on the part of health plans and providers have seriously eroded trust in all relationships. The recent highly publicized Institute of Medicine report on the high number of errors and related deaths in the healthcare system has also increased consumer anxiety. This, however, provides an opportunity to establish a new trusted agent entity that could provide this service.

Consumers appear willing to assume such new and expanded responsibilities. As Dr. Koop recently emphasized , "Baby boomers, who have historically set much of the nation's agenda and are its largest cohort, are making health care decisions for their children and parents. Baby Boomers are information junkies. They want to know what's in their doctor's heads, which is going to make doctors work smarter-and that will lead to better care."

Consumers are also increasingly concerned over the privacy and confidentiality of their medical records, especially who has access. Numerous disclosures about the transparency of current record keeping increases the sense of distrust. To date online access has not sufficiently addressed security concerns. A California Healthcare Foundation survey found that 75% of respondents are concerned about health Websites passing their personal data to other organizations without permission; 17% said that they do not use the Internet to gather health data for privacy reasons. The poll also showed, however, that 80% of respondents agreed that the existence of Web privacy policies "has a positive impact on their willingness to engage in online health activities." As online usage increases, online collection and interpretation of individual medical data becomes easier, it will be viewed as a more secure alternative to entrusting medical records to a variety of fragmented providers. But, as the above indicates, security and confidentiality must be high and unquestioned priorities.

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Providers

Any provider that provides medical services to the end user can use online medical record technology. There are over 500,000 potential medical service providers that can benefit including office based practitioners, acute care hospital systems, emergency room and other urgent care providers, home health care, as well as health care plan and health care insurance companies. All of them need better more sophisticated management tools. Some of these entities (and companies within these industries) will adopt Internet medical record keeping more rapidly than other segments because of the role technology plays in their current business model and operations. Throughout the development of PatientDirect providers will be a critical partner.

B

Provider Networks,Health Plans and Insurance Companies

Provider Networks, health plans and insurance companies are also heavily involved in medical record maintenance, storage, and transfer. Although online medical records will change the role of these organizations they will still be vital for the updating and interpretation of these data and for the provision of services based upon them. Many

providers have long been attempting to build comprehensive electronic medical record repositories within their own systems to facilitate online retrieval and storage to boost revenues, enhance productivity, and increase their own Internet exposure. Currently each service provider or health care system assumes responsibility for maintaining and updating individual medical records for all their patients. This means an individual patient has multiple versions of his/her medical record in different locations. Because of the fragmented and immature development of electronic records throughout the medical services industries, attempts to resolve these various versions and provide an accurate and updated version at the point of care has not been successful. Certainly relying on providers with their widely varying individual approaches to record storage, as the primary agent to provide and maintain an integrated record has not been successful. PatientDirect will strive to use its technology to help them achieve this integration. The consumer is an untapped but very attractive avenue to provide information and decision support at the point of care. Because there is already heavy government regulation and the current draft HIPPA regulations will create new mandates to encrypt and secure all medical record data electronically PatientDirect will use these mandates as a market driver.

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Methods for Online Medical Record Presentment

With the advent of the Internet there are three main methods for electronic medical record presentment. One of the methods implemented by some early Internet companies has been the 'single personal medical record web-site.' A second approach used by some providers is to 'aggregate' individual medical record data compiled as the result of system encounters at a specific web-site that provider associated clinicians can visit to obtain aggregate results. There are also specific disease management offerings that closely monitor patient's conditions in order to improve compliance and outcomes. Many of these are going online. With the exception, however, of PatientDirect we are not aware that the industry offers an approach that collects all personal health and medical record information by the individual independent of the provider or healthcare system.

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Single personal medical record web site

The approach some companies have used to enter the online medical record market is to provide the consumer the ability to enter vital statistics and other health care related data and then make this information available at the company's web-site. Consumers go to the company's web-site (i.e. 4healthylife.com or medicalrecords.com) and enter the portion of their medical record known to them This "pull" approach presumes that consumers will take the initiative to create, update, verify, and maintain their medical data. If consumers want to enter or update data from other electronic sources they must do so manually. Opportunities for transfer of medical data to providers are also limited or non-existent. Decision support capabilities or alert systems are primitive or non-existent.

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Aggregate or Web –Based Clinical Data Repository methods

Some healthcare IT vendors, Careinsite,. MedicaLogic Logician, for example, have proposed consolidating medical records at a distinct web-site managed by the vendor. In essence, components of the medical record are sent to a relational database and authorized users (but not patients) can receive and interpret individual and/or aggregate data. It simplifies the process for providers as they have fewer systems to go to obtain comprehensive medical record information on their patients. The individual consumer, however, does not directly control the medical record data, which is limited to that inputted and produced by selected providers not a comprehensive record.

Disease Management on the Web

The small disease management industry is increasingly recognizing the advantage of tracking their client's health using the Internet. Entities like ProMedex (private) do this in a traditional fashion with a variety of screens in which patients enter data and their condition is tracked by nurses. Health Hero is pioneering the ability to download automatically key ongoing health data such as blood glucose levels for diabetics in order to improve management. In most of these efforts the Internet is a component of a larger disease management effort. Some of these entities, however, could become likely acquisitions or marketing partners for PatientDirect.

PatientDirect collection and interpretation

The solution presented by PatientDirect allows the individual patient to control and then send their medical record directly to each of their providers. Providers can then open their patient's medical records, and use them to provide medical services from their desktops. This solution requires a direct delivery mechanism i.e. Internet, e-mail, personal floppy disc but keeps the individual in direct connection and communication with their medical records.

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PatientDirect

Company Description

PatientDirect is an online individual medical record collection and interpretation service provider, offering individuals the ability to CONTROL personal medical record information and UNDERSTAND their implications for their care.

B

PatientDirect's Solution

PatientDirect enables individuals to provide online personal medical record information to their providers and other authorized users via email and the Internet. PatientDirect's online medical record integrates with the provider's existing systems to extract data, and allows the provider to retain control over proprietary databases. The company's solutions focus on the growing consumer use of the Internet, the patient's desire to maintain

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control, insure accuracy, and control distribution of sensitive medical information, as well as emerging HIPPA regulatory demands for patient notification of all medical record transmittals. It also acknowledges the provider's need to become HIPPA compliant while improving their current medical record systems, enhance customer relationships, and improve efficiency of operations and billing. All products are generic formats for the individual owner of the individual medical record but are tailored solutions to a given provider, insurance plan, employer, etc.

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Employees

Currently, the founders run PatientDirect. In addition to their formal roles founders will lead all initial technical development and alliance efforts. Upon funding, initial hiring will focus on content, GUI, and technical developers. As clients are signed on, customer service and support personnel will be added.

Location and Facilities

The company has secured temporary free office space at The University of Virginia. The company anticipates 15 employees by July 2000. Suitable office space in a low cost area offering access to powerful data lines will be needed. This will most likely remain in the Charlottesville VA or Northern Virginia areas.

Operations Plan

PatientDirect's post funding launch will focus on all resources and logistics required to deliver the service by first quarter 2001. The focus will be on hiring and product development.

Hire: Immediately hire content, GUI, and technical developers. GUI and technology skill sets are vital and aggressive hiring will occur starting the day of funding. In order to accelerate development certain components of development may be out sourced. Accelerate alliance and co-marketing agreements with pilot partners. Alliance, marketing agreements, and acquisitions will be key components of the rapid growth necessary to be first to market early in 2001.

PatientDirect Services

PatientDirect

PatientDirect offers a full service individual medical record collection and interpretation solution for persons with chronic or ongoing medical service needs. PatientDirect will collect and compile data from various locations of an individual's existing medical records to create an enhanced online version. This customized medical record will contain capabilities and information sources selected by the individual accessible through successive mouse clicks.

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The operations flow of this service is also designed to integrate smoothly with the provider's existing workflow. PatientDirect will strengthen encounter and the provider's claims processing and patient care. The online medical record presented to the provider in their desired format. The process involves the following steps:

1. Patient/Consumer registers for PatientDirect.
2. Requests and receives copies of existing medical records from current providers
3. Online medical record created, patient can receive all decision support services including definitions of procedures and laboratory tests; normal ranges for all medical data, alerts for potential medication interactions, connections to recent articles related to patient's condition, etc.
4. The patient can send authorization for medical record transfer. PatientDirect software translates this medical record information into its database. For each new encounter, PatientDirect generates a customized electronic medical record. The electronic recorded is emailed to the individual and the provider. Alternatively the record can be accessed through the Internet.
5. The provider receives the records, reviews it, and provides services and updates based on new data generated during the encounter.
6. PatientDirect processes the responses, For each authorized encounter, an encounter transaction form is submitted
7. The transaction is processed
8. An execution report –certification authority?- is returned

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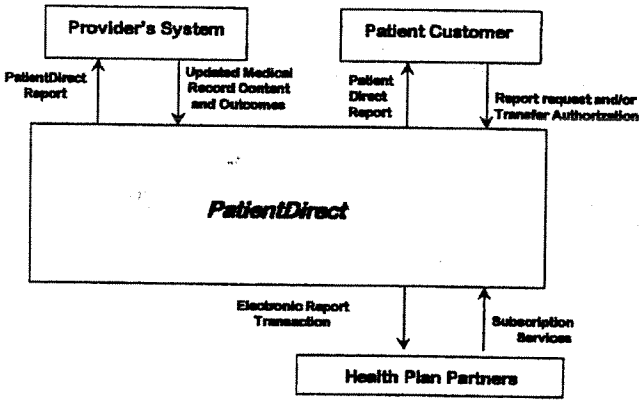

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Value of PatientDirect to the Patient/Consumer
The main benefits of using PatientDirect for the patient are CONTROL and UNDERSTANDING. The individual also saves time by not having to fill out paper registrations forms at each visit, not having to check that allergies and new medical data has been entered, and not having to ask for copies of recent tests. For each patient-

C

provider encounter through PatientDirect, the consumer is given the opportunity to automatically generate an update of their medical record.

PatientDirect also provides the following benefits to an individual user:

Direct access to all essential and critical medical record data
Control over access and transfer of all medical record data
Ability to obtain individualized interpretation and understanding of collected data
- -explanations of completed or anticipated tests and procedures
- -normal ranges for all results
- -medication alerts
- -link to appropriate web sites/news content

Assurance that current accurate information is available to providers regardless of treatment location or prior contact

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PatientDirect provides the following benefits to a provider:

Direct connection with accurate and updated patient's medical records
Reduction in operating costs associated with maintaining and updating personal medical records
Superior data management and integration of information from other providers
Control over medical record formatting issues
Assured Security and compliance with HIPPA regulations

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Patient Direct provides the following benefits to both patients and providers

Enhanced Chronic Disease Management: PatientDirect can assist the individual with decision support services related to their chronic condition particularly medications and ongoing disease management. Feedback can be individualized to the person based on both records and past utilization patterns. Such efforts have been shown to enhance compliance and improve patient outcomes while reducing health care utilization from 7 to 17 percent (Fries)

Individualized Online health promotion – An individual's medical record is a valuable channel that can present customized health promotions to an individual. PatientDirect will analyze medical record data and present suggestions and plans that are applicable to individual user. This one-to-one health promotion approach will provide higher responses than traditional generic promotions.

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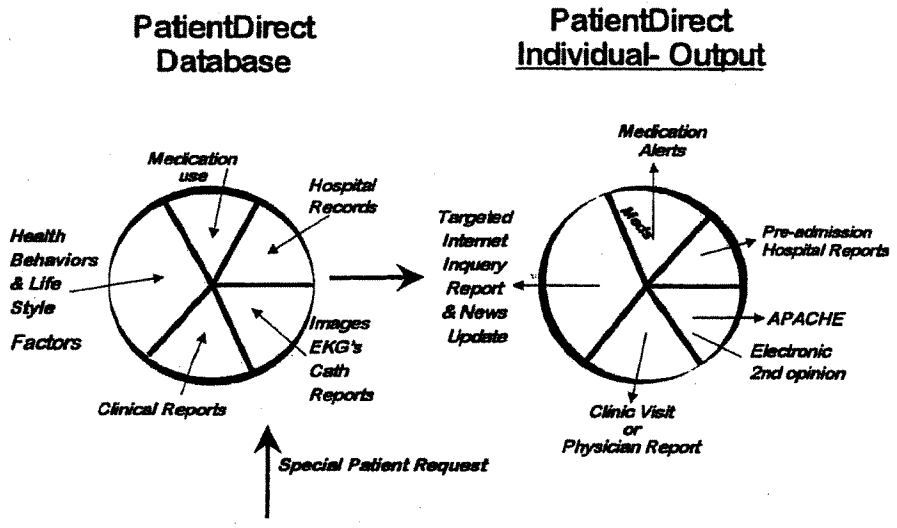
Enhanced patient support – Call desk or other authorized case managers, patient representatives, will be able to view the online medical record in formats identical to the

individual patient's copy. This will enable them to better educate and serve patients and their needs.

Web Links- will also be established with other support services that are applicable to the individual patient. There will also be set-ups for links to providers' web sites and direct e-mail between the patient and the provider and the health plan. On the basis of the individual's medical record PatientDirect will suggest appropriate questions.

Enhanced communication , reduced liability, and cost savings from using PatientDirect



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Eliminate operating costs from streamlined visits - Costs eliminated include staff time, paper, printing, and verification expenses. PatientDirect will present a streamlined and targeted medical record for the provider with information tailored to the type and anticipated needs of the encounter. This will reduce the time needed for the provider to review the record. This will enable the provider to spend more time with the patient or to see more patients within given clinic session. The provider will also be able to use PatientDirect's capabilities to update and maintain their records with information provided by the patient. Numerous studies have documented the lack of such communication and information transfer during patient-provider encouters. Poor communication has been identified as the primary factor leading to noncompliance with prescribed medications and treatments. It is also the most common reason cited in patient malpractice suits against providers.(refs)

B

Eliminate discretionary visits-

By permitting the provider to access and review all current critical information on a patient including current medications and to access decision support systems accessible to both the provider and the patient, it will be possible to avoid selected ongoing patient management visits

Data Management
Control - The individual maintains control over all personal medical record data, the provider maintains control of all process, content, and outcome and billing data and patient relationships. At no time does PatientDirect intend to intrude on the patient-provider relationship, rather it will enhance that relationship. PatientDirect allows providers to designate their own electronic medical record format and promotions. All of PatientDirect's client databases will remain confidential.

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HIPPA-The draft HIPPA regulations contain important new mandates that will have at least two important impacts on the US medical system. First it will accelerate the use of electronic medical records, increase the need for security in transmittal and force formal recording and notification of all medical record transfer. It is also our belief that the regulations will grant individuals an explicit right of access to their medical records data and an implied license to author a unique compilation of these data in the form proposed for PatientDirect.

B

Need more HIPPA Details here

Data storage and access - PatientDirect provides a graphical browser interface that is user friendly for the end user regardless of operating system. The system's database will permit storage of medical record data online.

Security
The individual's medical record number is neither transmitted over nor stored on the Internet. The individualized identifying information resides only in the secure database, and the transaction is over a dedicated private line. Additionally, the deployed system will have a firewall between the web access and the core database. To insure state of the art security, PatientDirect will devote significant resources to having security experts on staff and utilize the services of web security consultants.

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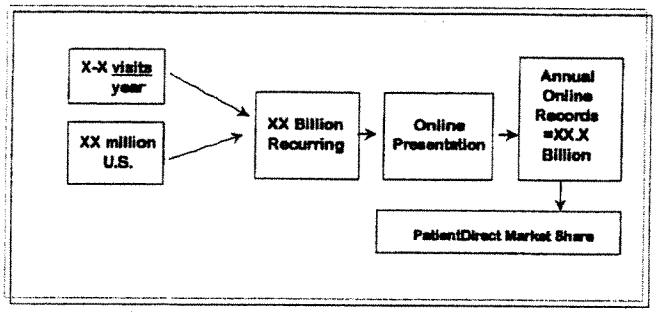
In addition, PatientDirect will constantly log all activity. To prevent fraudulent transfers, daily reconciliation of all records will be conducted prior to the close of business each day.

PatientDirect

Market Research and Analysis

Overall Online Medical Record Market
The total recurring market in the US includes office and clinic based practices, hospitals, sub-acute, and long-term care facilities, emergency rooms, urgent care providers and home health care. As the following Table illustrates, individuals total approximately X to XX encounters with these type of facilities per year, generating over XX billion encounters a year in the US alone. Facilities spend an average of $X.XX per encounter to update, confirm, and process individual medical records during these encounters. As

figure 2 illustrates, savings from EIMR can reach $X.XX per encounter when all aspects of patient recording and subsequent billing costs are included.



Therefore, the potential for total savings is estimated to be between $XX billion to $XX billion annually depending on the type of the encounter. Electronic Medical Record vendors, including PatientDirect, will compete for a share of a market forecasted to reach $X billion in the year 2000 and $XX billion in the year 2005.

The Need for a New Trusted Agent

As originally envisioned, health plans were to serve as the individual's representative to the medical service system. Their objective, as the name Health Maintenance Organization implied, was to maximize the use of health promotion, prevention, and treatment strategies for their clients. As such it could be envisioned that these entities would become "trusted agents" for their clients, assisting them in navigating and coordinating the health care service sector. By focusing on short-term profits, by maximizing enrollment growth and minimizing investments in information technology and other infrastructure US health plans have not achieved this status. The current backlash against health plans-- with consumers demanding the right to sue for restricted access-- is indicative of the public's current attitude. A 1998 survey by the Kaiser Family Foundation found that 36 percent of Americans perceived managed care organizations as doing a "bad job" in managing trust-up from 21 percent the year before. This situation, however, provides an important opportunity for offering PatientDirect services directly to consumers as control and reassurance over the actions of these plans.

Factors influencing adoption of online medical records

The online medical record collection and interpretation industry is still in the embryonic stage. There exist several products and services in the initial stages of deployment, which capture in part, the benefits. PatientDirect is committed to conducting sufficient needs analyses with consumers to identify those aspects of online medical record collection and presentation that best serve their needs. Growing retirement communities such as

Charlottesville, Va. and similar communities in North Carolina represent strong potential target areas due to high levels of computer usage and growing affluent but elderly and frequently chronically ill population bases. Growth in Internet usage and the extension of the Internet to include medical service encounters are important catalysts that will impact the growth of this industry.

Internet growth
Service applications on the Internet grow in tandem with the overall acceptance and usage of the network. Internet content is growing at 140% a year, which is driving people of all demographic segments to increase Internet usage. The explosive growth of the Internet has opened the doors for a shift in the medical record industry, from focusing on enterprise-wide electronic medical record system to individual or community and health plan based electronic record keeping and interpretation. The following points summarize the increasing acceptance of the Internet.

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Internet traffic is doubling every 100 days. In 1994, 3 million people were connected to the Internet. By the end of 1997, more than 100 million people were using it.

Number of users globally increased by 150% from 40 million in 1996 to over 100 million people in 1997.

Number of US users measured in November of 1998, increased 16% since May 1998, to 72 million adults.

Internet commerce will likely surpass $300 billion by 2002.

Growth in online medical decision support

33.6 million people in the US and Canada had made a health-related inquiry on the web by the end of 1998, there will be 52 million online information seekers in 2000.

Competitors

Internet health care applications can be classified into five "C's";Content, Commerce, Computer Applications, Connectivity, and Care.(ref.Goldman-Sachs)

Content: Web sites that provide information with target audiences of consumers and physicians. Examples Medscape, Web MD

Commerce: eSellers and eMarkets
Examples PlanetRx, Drugstore.com, Americas Doctor

Computer Applications:"Thin" client-server computer applications-can be in direct competition with traditional healthcare "IT" firms to provide single web browser interface to view or exchange information with multiple legacy applications.
Examples Healtheon, CareInsite, MedicaLogic, Eclipsys/Health Vision, IDX

Connectivity Link, usually within a closed network for exchange of information for a fee per transaction-also called electronic data interchange (EDI) networks. An open network is the public Internet and an ISP for connectivity. A closed network also uses Internet but has EDI.
Examples Envoy, National Data Corp, Healtheon, CareInsite

Care Internet technologies used by consumers to enable new forms of providing or managing health care (a.k.a. telemedicine)
Examples: Life Masters, HealthHero, Global Medic, and VidiMedix

Although any of the companies in the above five sectors could be potential competitors, the following are PatientDirects current main potential competitors.

Healtheon/WebMD
CareInsite
MedicaLogic
HealthHero
Medical records.com.

Addressing the competition
PatientDirect's focused approach , its developer's record of turning medical content into decision support products, and its alliance and marketing strategies will drive its success. The following are key points of differentiation, which provide advantages over competing approaches.

PatientDirect is the first entity to focus solely on integrating the healthcare IT marketplace through the development and dissemination of a comprehensive individually owned and individually distributed medical record service. The rapid increase in Internet usage, the far reaching implications of draft HIPPA federal regulations and the growing concern on the part of consumers about the safety and efficacy of medical decisions provide an historic opportunity to provide a new safe, cost efficient option for controlling medical data, meeting HIPPA regulatory requirements, and addressing the consumer's need for their medical record data to be accurate, updated, and at various locations.
Current or developing online services like CareInsite or MedicaLogic can provide medical record services, but only for the subset of information that is available from their provider networks. Any contact or medical information that the individual has that resides outside this network is not available. PatientDirect is also the only solution that is designed specifically for the individual to control the content, accuracy, and dissemination of their medical data as required by draft HIPPA regulations. First mover advantage is critical for PatientDirect; the first mover can offer the individual all the benefits of applying comprehensive Internet technology to the entire medical record collection and interpretation process. Once a user has signed on with PatientDirect, the

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user will reap the benefits of technology, and follow on competitors will be hard pressed to offer significant additional benefits.

PatientDirect Systems

Marketing and Sales Strategies

Our first market for PatientDirect is individuals and their family members who require complex and/or ongoing medical services from a variety of providers. This market is particularly attractive due to the large and growing number of such individuals within the US population. Indeed, estimates of the prevalence of chronic conditions taken collectively exceed the current U.S. population (See Figure). It is estimated by The Robert Wood Johnson Foundation that up to 90 million Americans have one or more of these conditions with sufficient severity to obtain office based consultations an average of 6 times annually-twice the national average of 3.

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Many of these individuals and their family members are closely involved and concerned with the quality of their care. PatientDirect bridges the gap for these individuals between the immature information technology of office-based providers that are substantially behind in their use of electronic medical record storage and decision support systems and the fragmented Healthcare IT industry. The latter has been slow to react to Internet possibilities and continues to attempt integration from a provider, system, or enterprise viewpoint not from a consumer perspective. This results in the following significant questions and issues for patients and consumers:

-Does this doctor know all about my medical history ?
-Will the drugs just prescribed interfere with my existing medications?
-Am I going to the right sort of specialist ?
-Do they know I had a bad reaction to sulfa drugs when I was young?
-What is going to happen if I have the operation?
-What are my choices and how do they compare?
-Am I likely to need nursing home care?
-What does this new lab result mean for my chance of recovery?

The following are also current concerns and their visibility will be raised and encouraged by HIPPA

-Who has copies of my medical record?
-Does the specialist have my latest EKG tracing?
-Did my records go to the right clinic?
-Did anyone besides the doctor look at it?
-Did I receive notification that my doctor sent my records to the hospital?

Various consumers care about particular aspects of these issues. Our first market for PatientDirect will be consumers that, because, of the burden of complex disease are heavily invested in negotiating the best care from multiple providers.

Through partnerships with online networks such as AOL and/or YAHOO we will develop a focused marketing plan that will position PatientDirect as the "gold standard" for medical record CONTROL and UNDERSTANDING by consumers and patients in the same way that APACHE is now recognized as the gold standard for decision support within the healthcare industry...***more details to come***

PatientDirect believes that alliance partnerships are an efficient and economical way to capture market share rapidly. We gain distribution outlets and cooperative marketing arrangements through application vendors who embed our API in their software. Besides relationships with major national online vendors such as AOL and YAHOO , we are also approaching more specialized software vendors—such as DXPLAIN and medical management systems-- that have traditionally offered their interpretive and decision support approaches for medical data to clinicians, pharmacists, and other providers—to offer these services directly to consumers using PatientDirect as the source of medical record data.
Because of the tremendous potential of this new market, competition does exist. Most major healthcare IT vendors are developing Internet enabled applications. Cerner Corporation, for example, became a major development partner in CareInsite. MedicaLogic also aims to automate the physician's office. There are also specialty applications within specific chronic diseases such as HealthHero. All of these company, however, are targeted at providers and none have achieved brand identity with the consumer.

Since the company is currently developing a prototype version of its PatientDirect solution, the company will need to follow a marketing strategy that involves two phases. Marketing in Phase 1 will be targeted at consumers that can be partners in the development of PatientDirect. Phase 2 marketing will involve the successful rollout of PatientDirect to a broader range of individuals.

Phase 1
The primary goal in Phase 1 is the successful development of PatientDirect. Secondary goals include establishing credibility within the healthcare IT industry and access to resources. This phase is estimated to last 12months.

Target Market
In Phase 1, PatientDirect's ideal target customer should fulfill the following criteria.

Either have or have a close family member with a significant and complex chronic disease i.e. AIDS, Congestive Heart Failure, Cancer, Diabetes, etc.
Agree to request access to medical record data and data files to assist in development of PatientDirect.

Provide alpha-testing site for PateintDirect's services.

Possess sophisticated Internet experience

Willing to share personnel and medical system experience with PatientDirect in needs analyses and design interactions.

Pricing - Phase 1

During Phase 1, PatientDirect will partner with customers to develop the product. PatientDirect intends to attract customers who meet the above mentioned criteria, by offering free services for all components of service. PatientDirect may extend this price moratorium for another negotiated period if it needs to attract key customers for development of PatientDirect.

Communication /Promotion - Phase 1

Promotion of this phase will be through Internet with all alliance partners (AOL/YAHOO)...

Phase 2

In this phase the company will roll out its PatientDirect solution to ....

Target Market

Customers in Phase 2 will fulfill the following criteria:

"Early adopters" and "innovators" of consumer health care.

Located in areas with high Internet usage.

Possess sufficiently complex medical record and need for coordination of services to generate greater visibility and usefulness for PatientDirect.

Pricing - Phase 2

We will continue to provide free software that will register new patients and permit them to both construct and assemble an online medical record. The online record would be compiled from data that the patient either entered directly or that was obtained by electronic transfer from existing sources. Associated free services might include the definitions and explanations of procedures and tests that are contained in their medical record, the ability to be linked to disease or condition specific web sites, and to tailor the transfer of news items related to their condition to them.

Other services such as review of their medications for alerts or potential interactions; and decision support or second opinion services such as are being developed by APACHE in its CV risk predictor would be charged on a transaction or subscription basis ??

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Transaction Fees

There will be two types of transaction fees; the first will be charged to the patient/consumer user for patient specific types of decision support services, medication

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alerts, and customized disease management programs driven off the medical record, the second will be a transaction fee assigned per authorized medical record transfer. This fee is meant to include the incremental value to the patient/consumer per transaction, including:

Reduced Registration Time
Reassurance that all-medical information is available and correct
Control over distribution and notification of all transmittals

Communication / Promotion - Phase 2
Promotions to attract Phase 2 will begin in Phase 1. Promotions in this phase will be on a larger scale and will occur simultaneously at multiple locations.

Internet targeting customers
Extensive joint marketing promotions with online networks such as AOL/YAHOO aimed at establishing Patient Direct as the gold standard for all medical records- The marketing themes will be CONTROL/UNDERSTANDING/REASSURANCE

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Signing up patients /consumers
Individuals and Household consumers will sign up for online medical record collection and interpretation either from hearing about PatientDirect from current users or by advertising of the service over the Internet. The consumer may sign up easily by either checking off a box on an advertisement or by accessing the www.PatientDirect.com web site. In either case, the customer provides their active email address and medical record locations. The customer can select any preferences in service, including whether they prefer to update and review their medical records via the web site or through direct email, and whether they want to authorize each medical record transfer individually, or authorize automatic updates to selected providers. PatientDirect will input this criteria into the customer medical record information in the system database.

Maintain Control. Guarantee Accuracy. Gain Understanding.

OWN your own medical record.

No fear of unauthorized viewing. Available in any emergency at any time.

Know where your medical records are all the time and who is looking at them.

Prevent unauthorized access.
Receive alerts and advice based on the best medical evidence combined with your data.
Just fill out the form below, and your medical data will finally be yours and under your control

This service is:

Easy

You register and we help you get your medical records from all your doctors, clinics and hospitals.

You can review your medical record at anytime, in the privacy of your home.

You can transfer all—or any part of it--to your doctor or other health care provider knowing it is accurate and up to date

Transfer with a few mouse clicks. Receive a receipt.

Secure

Your individual identifying information is not transmitted as part of your medical record-only the provider to who you authorize transfer can identify it as belonging to you

Questions? Call 1-800- or go on the internet to www.eIMR.com

PatientDirect

Management and Ownership

Key Management and Operating Personnel

To be completed

Planned Additions to Current Management Team

Director of Needs Assessment

A key member of our team will be a content expert with extensive experience in designing consumer web sites. As this is an important component for success, significant equity is reserved to attract a top candidate for this role.

Director of System Development

Experts in GUI for consumer/health

Legal Structure

The company name, PatientDirect, will be reserved for incorporation. The company will be initially formed as an S Corporation.

Owners

The founders and owners of PatientDirect Inc. are the same as the current management team mentioned above.

PatientDirect

Financial Plan and Projections

Financial Summary

From incorporation to the formation of PatientDirect, PatientDirect has been financed through founder stock and seed capital from ***details to come.*** We are now raising $20 Million in two rounds----$5 million to officially launch the service (from AMS and others)and an additional $15 million by end 2000-early 2001 to expand the company and enable us to achieve profitability by the second quarter 2002. The company's financial projections are based on conservative assumptions of Internet usage, growth of electronic medical encounters on the Internet, and number of users benefiting from PatientDirect. Based on these assumptions, PatientDirect will achieve revenues of $XX.X million and net income of $XX.X million in 2005.

PatientDirect has been designed as a company that can generate earnings as well as produce great investment returns. The plan has been designed with at least two potential liquidity events. In the event current Internet valuations continue, we could provide liquidity in the form of ?reverse merger with AMSI ? Alternatively we expect consolidation as key health care portals emerge as preferred entry points. In this case the winning players will turn to content to maintain and expand their user base. Overtime more and more sophisticated content and member services will be required. Production of the type of sophisticated proprietary intellectual content PatientDirect is not the focus of current healthcare portals and would be very attractive to acquire.

For example, Healtheon/WebMD recently acquired the electronic health insurance claims processor, Envoy Corp., from Durham, N.C.-based Quintiles Transnational Corp. With the acquisition, Healtheon/WebMD, which provides online consumer health information and manages medical records, becomes the largest Internet site linking doctors, health insurers and patients. After the purchase, Healtheon/WebMD CEO Jeff Arnold said the firm will process around 2 billion health insurance transactions annually, with an average fee of 30 cents for each transaction.

Financial Projections

Financial projections were created to model the effects of certain assumptions of our business model. Through our due diligence, we discovered broad estimates for the cost of online medical record presentation.

Estimates ranged from $X.XX to X.XX; however, we believe that a conservative $X.XX cost is reasonable and sustainable given the rising costs of staff and documentation requirements over the life of the projection.

PatientDirect's revenue model includes two parts, an overall support fee paid through advertising and per transaction fees for decision support and document transmittal. Total Clients

2000-approximately 50,000 individual users

2001-approximately 250,000 individual users
2002-approximately 2 million individual users

The company achieves positive cash flow in Q2 2002, and the cumulative cash draw down peaks at $X.Xmillion dollars.

Expenses
Transaction Fee
The insurance company or EDI vendor that executes the transfer will collect $X.XX per transaction. We anticipate this rate will decline as insurance companies compete for this option and volume increases..

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PatientDirect - Technology and Architecture

Product Description
PatientDirect is a consumer support and consumer-to-medical system Internet document transmission service that offers an integrated and secure method of controlling and interpreting medical record data. We use a second opinion/discount broker strategy in which to derive revenues-and high margin earnings-from selling clinical decision support and document transaction-(certification authority)- that are accessed through free software that maintains and protects all the individual's medical records.

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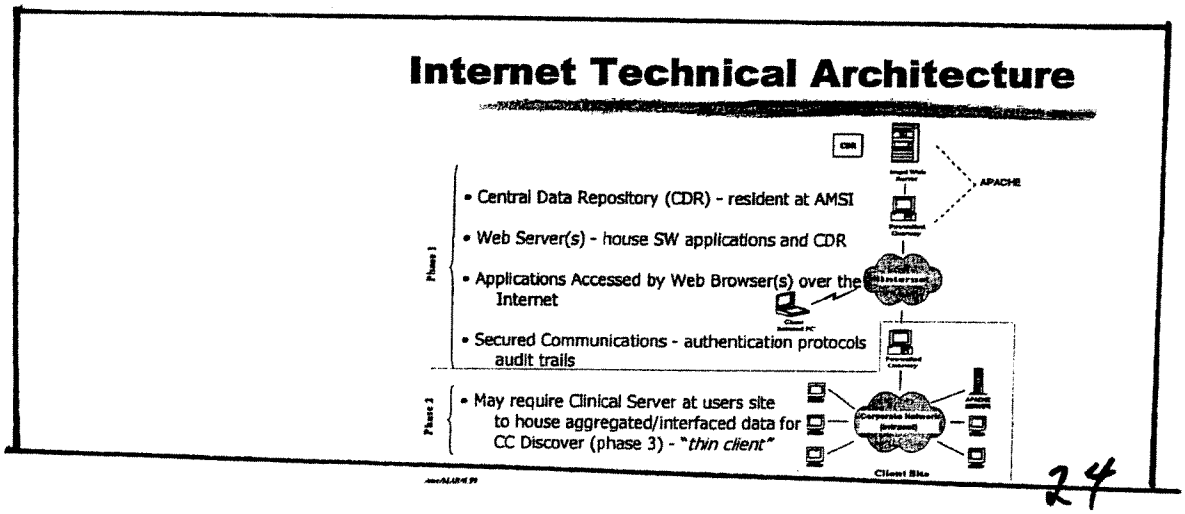
Our customer-focused approach dictates that this service be available from browsers as well as desktops and enterprise applications. Our API allows our alliance partners the ability to offer-and earn commissions on certain "PatientDirect enabled"-decision support and record transmission services.
PatientDirect service uses an XML/HTTP protocol with encryption. SSL is also used as needed for the browser-based version of the product. Our algorithms and other methods of interpreting medical record data are unique and we are investigating patent opportunities. We will also expect to be involved in efforts to create an Extensible Markup Language (XML) data exchange standard for the medical sector. This standard and others like it will lower our integration costs while helping to solidify our position in the medical marketplace.



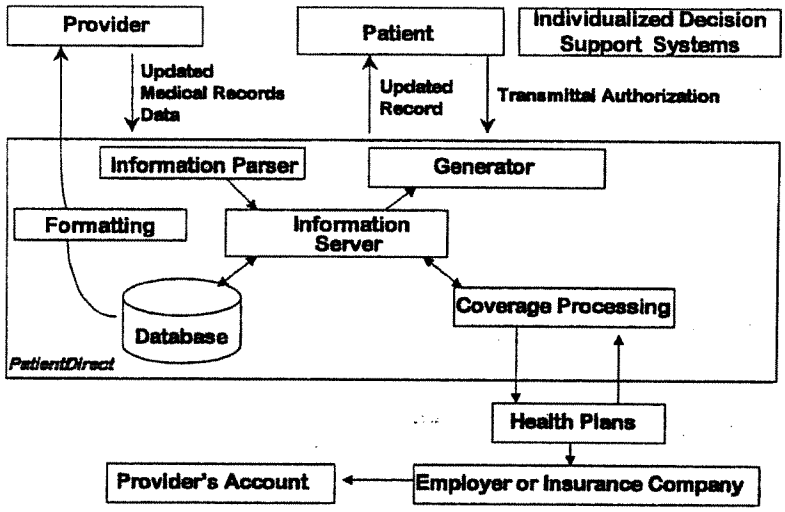
C

The premise behind the technology is to provide the benefits of the PatientDirect service to the patient/consumer without requiring the health plan or the providers to modify their existing system. The online individual medical record service drops directly into their existing architecture, data formats, and workflow for straightforward systems integration.

Information Parser

The information parser component interfaces with the health plan's and provider's existing registration and information systems. The legacy medical record systems of plans and providers can use a wide variety of data formats, the parser extracts the relevant information from the formatting. The PatientDirect workflow filters the data to extract the key information from the data stream. The key point is that the information for online medical record collection is provided directly into the provider's existing format, the provider does not need to make any upgrades or changes.

System Components of PatientDirect



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The core technology is to build complex applications that simultaneously can be run on a thin-client and can be cost-effectively tailored to the mainstream health provider. Examples of such existing applications are Confer(private) and OrganicNet (private). These companies have developed architectures that require an underlying data model describing the universe of complex relationships and entities within healthcare and additionally includes tools for rapid adaptation to obscure formats that are unique to a specific provider. Overtime a new client's format will be the same as an existing format, so that their data can be immediately integrated with PatientDirect. But the level and complexity in building these "codeless" development environments acts as a major barrier to entry and is a huge competitive advantage.

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Information Server

The information server manages all functionality of the system, including processing both incoming and outgoing information. The system runs on a Windows NT Server workstation, linked to SQL Server via ODBC connectivity. The web-enabled applications are implemented in Active Server Pages (ASP). An alternative approach is to download a thin engine (4MB) that, in a minute or two at run time, builds the client that is stored as data on the server. Sophisticated caching techniques limit the overhead involved in this process to the first run of the day. Event the most complex applications can be very responsive in a thin-client, real-time environment under this model (OrganicNet).

This server includes:

1.A corporate presence at www.PatientDirect.net
Provides company and service information via the Internet.

2.Consumer access through www.PatientDirect.com
Supports confidential access to facilitate individuals automatically uploading updated medical record information and interpretation content, which they want incorporated within the online medical record.

Facilitates patients' access to their account via the internet. They can view previous records and interpretations, and update their information.

3.Background Processes - The background server applications include:
Generator - automatically generates, formats, and sends medical record via email. The email is in HTML format, to facilitate interactive medical record presentment. Interactive components and features of the record viewing are implemented in VBScript and JavaScript ?????

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Transaction Processor

Transaction generation occurs via three methods:

When the individual medical record keeper responds to the medical record presentment, authorizing transfer to his service provider

When the individual visits web site to authorize transfer.

If the individual has authorized automatic transfers and updates to a provider, a transaction is generated when the provider receives the medical record information.

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In these cases, the system generates an electronic transaction to transfer records to the provider; this transaction is in the form of an ETF (Electronic Transfer Form Clearinghouse) electronic record. The design allows for the incorporation of medical record number back ends, and HL7 compatibility. HL7 is a universal standard for the electronic exchange of medical data and is compatible with the software packages offered by all major healthcare IT vendors.

The completed transfers are consolidated into a monthly reconciliation report. Currently, the reconciliation report is designed to be compatible with the ???? standard, which is both human and machine-readable.

Record Database

The record database stores all customer data in a SQL Server database. This includes all customer information, including location, status, current and prior usage and record transfer information, and any other information provider by the individual. In the case where the individual uses the services of more than one provider, the information is linked. Other information stored includes dates of prior updates, responses to informational data included with the electronic record, and customer driven inquiries about medical record and or/service information. SQL server includes robust features to insure data integrity and transaction reconciliation and security.

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Security

The design uses SSL (secure sockets layer) encryption for security. This is the standard security measure used for the most secure data transfers over the web, based on public key/private key RSA encryption technology. Note that the individual's medical record number/personal identification number is NOT transmitted over the Internet. When the customer authorizes transfer a transaction is generated, but no personal identifying information is transmitted. The medical record number information resides only in the secure database, and the transaction is an ETF transmission over a dedicated private line. Additionally, the deployed system will have a firewall between the web access and the core database. To insure state of the art security, the company will devote significant resources to having security expertise on staff, and using the services of web security consultants.

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In addition, PatientDirect will provide immediate confirmation of transfers of medical record information to the individual. To prevent fraudulent transfers, daily reconciliation of all accounts will be conducted prior to the close of business each day.

Claim Chart for U.S. Patent Application No. 09/816,152
with regard to claims rejected under 35 U.S.C. § 103(a) in reference to Malik

Claim No.	Claim feature	Exhibit Disclosure Location Page No./Paragraph
13	wherein said collection complies with a federal or state standard of privacy and security.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
14	wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
15	wherein said collection complies with all state standards of privacy and security for the geographical area in which the system operates.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
20	A broad-band, computer-based networked system for individual control and management of electronic medical records comprising;	Page 1/B; Page 4/A; Page 7/A; Page 8/A,B,C; Page 11/A,B; Page 12/C; Page 13/B; Page 14/C; Page 24/B,C; Page 25/A; Page 26/A.
20	a plurality of medical records representing a plurality of persons wherein	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
20	said plurality of medical records complies with a federal standard of privacy and security and	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
20	the medical information of at least one medical record of the plurality has been vetted, such that the medical information of said at least one medical record is better than exists at a source site from which the medical record was obtained and thereby is not subject to repudiation.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
21	which allows for certification of said medical records.	Page 1/A; Page 4/A; Page 11/A; Page 12/A.
22	wherein certification represents a predetermined degree of completeness, accuracy or both to said medical records.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
23	which allows for vetting of the medical information of said medical records.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page

		12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
24	wherein vetted medical records have been reviewed and corrected or annotated for errors, discrepancies and anomalies.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
25	which allows for non-repudiation of the medical information of said medical records.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
26	wherein non-repudiated medical records are primary for treatment of the person to whom each medical record pertains by health care providers.	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
27	wherein the plurality of medical records complies with the Health Insurance Portability and Accountability Act of 1996.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
28	which further complies with a state standard of privacy and security.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
29	wherein access to any one medical record is restricted to the person to whom said one medical record pertains or to others designated and authorized by said person.	Page 1A; Page 4/A,B; Page 6/C; Page 7/A; Page 8/A,B,C; Page 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 14/B,C; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B; Page 27/A.
32	wherein access to the electronic medical record database complies with a federal standard of privacy and security.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
33	wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
48	wherein said secure database complies with a federal standard of privacy and security.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
49	wherein the federal standard is the Health Insurance Portability and Accountability Act of 1996.	Page 1/B; Page 7A; Page 10/A; Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.
50	which further complies with a state	Page 1/B; Page 7A; Page 10/A;

	standard of privacy and security.	Page 11/A; Page 12/B; Page 14/A,B,C; Page 17/A,B; Page 27/B.

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Claim Chart for U.S. Patent Application No. 09/816,152
with regard to claims rejected under 35 U.S.C. § 102(e) in reference to Segal

Claim No.	Claim feature	Exhibit Disclosure Location Page No./Paragraph
1	A broad-band, computer-based networked system comprising	Page 1/B; Page 4/A; Page 7/A; Page 8/A,B,C; Page 11/A,B; Page 12/C; Page 13/B; Page 14/C; Page 24/B,C; Page 25/A; Page 26/A.
1	a collection of patient-based electronic medical records containing medical information of a plurality of persons, wherein	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
1	the medical records are obtained and electronically compiled from a plurality of sources	Page 1/A; Page 2/A; Page /A; Page 7/B; Page 8/A,B; Page 10/B; Page 11/A,B; Page 12/A,B; Page 13/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A; Page 27/A.
1	one or more medical records of the collection possess a characteristic of non-repudiation such that the medical information contained within said medical records is verified as accurate and correct	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
1	the medical record of a person is transmissible in whole or in part only to that person and others authorized by that person	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
1	medical record can be supplemented with additional information; and	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,C; Page 9/BPage 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
1	additional medical records for additional persons may be added to the collection	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,C; Page 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
1	a secure access for allowing each person to access only their own medical record; and	Page 1A; Page 4/B; Page 6/C; Page 7/A; Page 8/A; Page 12/B; Page 14/B,C; Page 27/A.
1	at least another secure access for allowing	Page 1/A; Page 4/A; Page 6/C;

	said others authorized to access only that person's medical record	Page 7/A; Page 8/A,B,CPage 9/B; Page 10/B; Page 11/A,B,C; Page A12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
2	wherein said medical records are electronically compiled by direct input or digital scanning of written information into a computer-readable format	Page 1/A,B; Page 3/A; Page 4/C; Page 5/A,B,C; Page 7/A; Page 8/A; Page 11/A,B; Page 14/A; Page 16/A; Page 17/B; Page 20/A; Page 21/A; Page 24/C; Page 25/A; Page 26/A.
3	wherein the sources are selected from the group consisting of hospitals, clinics, physician's offices, pharmacies and combinations thereof	Page 1/A; Page 2/A; Page /A; Page 7/B; Page 8/A,B; Page 10/B; Page 11/A,B; Page 12/A,B; Page 13/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A; Page 27/A.
4	wherein said medical records are transmissible through the Internet	Page 1/A,B; Page 3/A; Page 4/C; Page 5/A,B,C; Page 7/A; Page 8/A; Page 11/A,B; Page 14/A; Page 16/A; Page 17/B; Page 20/A; Page 21/A; Page 24/C; Page 25/A; Page 26/A.
5	wherein the medical record for each person contains one or more of: a table of contents, an index, a source notation for information contained within the medical record, an electronic search tool, annotations for errors, linked annotations for errors, treatment options, health care choices, verification standards and news items relevant to the information in the medical record	Page 1/A; Page 2/A; Page 3/A; Page 4/C; Page 5/A,C; Page 6/C; Page 7/B; Page 8/A,B,C; Page 11/A,B; Page 13/A; Page 14/A; Page 16/A; Page 17/B; Page 20/A; Page 26/A.
6	wherein the secure access and the another secure access comprise passwords or encryption keys	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,CPage 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
7	wherein the others authorized are selected from the group consisting of physicians, nurses, hospitals and health care institutions	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
8	wherein all of the medical records of the collection possess the characteristic of non-repudiation	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page

		17/A,B; Page 24/B.
9	wherein said non-repudiated medical record is primary for treatment of a person to whom said non-repudiated medical record pertains	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
10	wherein each medical record is certified as accurate	Page 1/A; Page 4/A; Page 11/A; Page 12/A.
11	wherein the medical information of each certified medical record is certified by a person to whom the medical record pertains, by the source from which said each medical record was obtained, by a system provider or by a combination thereof	Page 1/A; Page 4/A; Page 11/A; Page 12/A.
17	further comprising a fee which is assessed for maintenance of a medical record	Page 6/A,B; Page 20/A; Page 24/A.
30	A method for creating an accessible electronic medical records database comprising	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
30	obtaining and compiling a medical record pertaining to a patient	Page 1/A; Page 2/A; Page /A; Page 7/B; Page 8/A,B; Page 10/B; Page 11/A,B; Page 12/A,B; Page 13/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A; Page 27/A.
30	determining accuracy and correctness of medical information within each medical record	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
30	electronically inputting said medical information within each medical record into a secure computer database containing other medical records; and	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
30	allowing said patient and those authorized by said patient access to said patient's medical record wherein access to all other medical records is blocked	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
31	wherein determining accuracy and correctness comprises vetting, identifying or linking errors or inconsistent information, or expunging clear errors in input	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.

34	further comprising updating the medical record database with additional medical information pertaining to said patient	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,C; Page 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
35	further comprising securely transmitting all or part of said patient's medical record to a third party as designated by said patient	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
36	further comprising displaying said medical record pertaining to a patient	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
37	An electronic database of medical records created and compiled according to the method of claim 30, wherein the medical information contained within said medical records is more accurate and correct as compared to those sources from which the medical records were obtained	Page 1/A; Page 4/A,C; Page 6/A,C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/B,C; Page 25/A; Page 26/B; Page 27/B.
38	which contains the entire medical history of at least one person	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
39	wherein each medical record is remotely accessible in whole or in part only by the patient to whom the medical record pertains and those authorized by said patient	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
40	A business method comprising: operating and maintaining a secure database of medical records containing medical information of many persons obtained from a plurality of sources	Page 1/C; Page 2/A; Page 4/B; Page 7/A,B; Page 10/B; Page 11/A,B,C; Page 12/C; Page 13/A,B; Page 17/A; Page 18/A; Page 25/A.
40	whereby each medical record is accessible through transmission pathways and only by the person to whom the medical record pertains and those authorized by said person, and	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,CPage 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page

		26/A,B.
40	accuracy and correctness of the medical information within at least one medical record is determined to be as good or better than exists at the source from which said at least one medical record was obtained	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
41	A method for integrating medical records to create a certified medical record database comprising	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
41	obtaining medical information from one or more healthcare sources for a plurality of patients	Page 1/A; Page 2/A; Page /A; Page 7/B; Page 8/A,B; Page 10/B; Page 11/A,B; Page 12/A,B; Page 13/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A; Page 27/A
41	electronically inputting all of the medical information obtained into a secure computer database to create medical records; and	Page 1/A,B; Page 3/A; Page 4/C; Page 5/A,B,C; Page 7/A; Page 8/A; Page 11/A,B; Page 14/A; Page 16/A; Page 17/B; Page 20/A; Page 21/A; Page 24/C; Page 25/A; Page 26/A.
41	certifying that each of said medical records meet one of a plurality of certification standards established by a service provider to create the certified medical record database	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
42	wherein any one of the certified medical records can be transmitted only to the patient to whom the record pertains or those authorized by said patient	Page 1/A; Page 4/A; Page 6/C; Page 8/A; Page 9/A,C; Page 10/A; Page 11/A,B; Page 13/A; Page 14/B; Page 17/A; Page 24/C; Page 25/A; Page 26/B; Page 27/B.
43	wherein the plurality of certification standards are selected from the group consisting of self-certification, certification by the service provider and combinations thereof	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
44	further comprising a step whereby said patient obtains an analysis of the medical record	Page 1/A,B; Page 6/C; Page 8/B; Page 9/B; Page 10/A,B; Page 11/C; Page 12/C; Page 17/B; Page 20/A; Page 24/A; page 27/A.
45	further comprising providing said certified medical record database with the characteristic of non-repudiation	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
46	A computer system for management of	Page 1/A,B; Page 2/A; Page 4/B;

	patient-based medical records comprising	Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
46	a database of medical records pertaining to one or more subjects	Page 1/A,B; Page 2/A; Page 4/B; Page 6/C; Page 7/A,B; Page 8/A,B,C; Page 10/B; Page 11/A,B; Page 13/A,B; Page 17/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A.
46	a receiver for receiving the medical information pertaining to said medical records from one or more senders	Page 1/A; Page 2/A; Page /A; Page 7/B; Page 8/A,B; Page 10/B; Page 11/A,B; Page 12/A,B; Page 13/A,B; Page 18/A; Page 20/A; Page 24/C; Page 25/A; Page 27/A.
46	a process for verifying that the medical information received is accurate and correct by at least vetting said medical information	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
46	a process for authorizing said senders and said additional receivers according to a set of rules; and	Page 2/A; Page 3/A; Page 4/A,C; Page 5/A,C; Page 8/B,C; Page 9/C; Page 10/C; Page 11/A,B; Page 12/C; Page 14/A; Page 17/A,B; Page 24/B,C; Page 25/A.
46	a transmitter for transmitting at least a portion of said medical records to one or more additional receivers; and authorization for authorizing said senders and receivers according to a set of rules	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,C; Page 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
47	wherein said database is a secure database.	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,CPage 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
51	wherein said receiver is selected from the group consisting of: modem, cellular receiver, infrared receiver, Ethernet card, facsimile, cable modem, satellite receiver, optical, analog receiver, Internet hub, and web-server	Page 1/A,B; Page 3/A; Page 4/C; Page 5/A,B,C; Page 7/A; Page 8/A; Page 11/A,B; Page 14/A; Page 16/A; Page 17/B; Page 20/A; Page 21/A; Page 24.
52	wherein said transmitter is selected from the group consisting of: modem, cellular transmitter, infrared transmitter, Ethernet	Page 1/A,B; Page 3/A; Page 4/C; Page 5/A,B,C; Page 7/A; Page 8/A; Page 11/A,B; Page 14/A;

	card, facsimile, cable modem, satellite transmitter, analog transmitter, Internet hub, and web-server	Page 16/A; Page 17/B; Page 20/A; Page 21/A; Page 24.
53	wherein said process of authorizing comprises public key encryption, digital signatures, biometrics, certificate authorities, or user passwords	Page 1/A; Page 4/A; Page 6/C; Page 7/A; Page 8/A,B,CPage 9/B; Page 10/B; Page 11/A,B,C; Page 12/A,B; Page 13/B; Page 17/A; Page 20/A; Page 25/A; Page 26/A,B.
54	wherein said portion of said medical records have the characteristic of non-repudiation	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
55	wherein said non-repudiated medical records of said one or more subjects are primary for treatment of said one or more subjects by health care providers not involved with creating said medical information	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
57	wherein said database is administered by a service provider other than said subjects, senders, and receivers	Page 1/A,B,C; Page 2/A; Page 3/A; Page 4/A,B,C,D; Page 5/A,B,C; Page 6/C; Page 9/A,B,C; Page 10/B; Page 11/B,C; Page 13/A,B; Page 14/A; Page 17/A,B; Page 24/B,C; Page 25/A,B.
58	further including vetting that allows said subjects to supplement said medical records with information relating to the accuracy of said medical records	Page 4/A,D; Page 8/A,B,C; Page 10/A,B; Page 11/A; Page 12/A,B,C; Page 13/B; Page 17/A,B; Page 24/B.
59	wherein said medical records are owned and controlled by said subjects	Page 1/A,C; Page 6/C; Page 9/B; Page 11/C; Page 12/C; Page 14/A; Page 21/A; Page 25/A.

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RELATED PROCEEDINGS APPENDIX

None